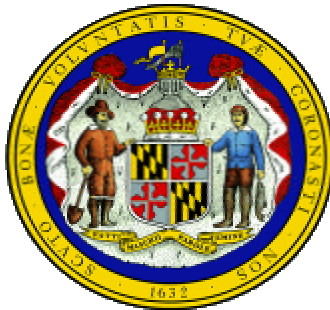


**White Paper:
Policy Issues in Planning and Regulating Open Heart
Surgery Services in Maryland**

Summary of Public Comments

MARYLAND HEALTH CARE COMMISSION



September 15, 2000

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I. INTRODUCTION

During 2000, the Maryland Health Care Commission will update the State Health Plan for cardiac surgery and therapeutic catheterization services. To encourage public discussion and debate in shaping the policy direction of the updated State Health Plan, the Commission prepared a ***White Paper: Policy Issues in Planning and Regulation Open Heart Surgery Services in Maryland***. This White Paper was designed to assist the Commission in the process of updating the State Health Plan by: (1) providing background information on cardiac care services in Maryland; (2) identifying key policy issues in planning and regulating open heart surgery services; (3) examining the impact of alternative policy assumptions; and (4) providing a framework for the Commission to obtain public comment on key policy issues prior to updating the State Health Plan.

The Commission released the White Paper for public comment on June 18, 2000. In response to the invitation for public comment, written comments were received from a total of 21 organizations and individuals:

- Adventist Healthcare, Inc.
- Anne Arundel Medical Center
- Carroll County General Hospital
- Dimensions Healthcare System
- Frederick Memorial Hospital
- Greater Baltimore Medical Center
- Greater Baltimore Medical Center (H. Carl Garthe)
- Health Services Cost Review Commission
- Holy Cross Hospital
- Johns Hopkins Hospital
- LifeBridge/Sinai Hospital
- MedStar Health
- Montgomery County Commission on Health
- St. Agnes HealthCare-Paul Dudley White Coronary Care Unit
- St. Agnes HealthCare
- St. Joseph Medical Center, MedStar Health, LifeBridge Health, Peninsula Regional Medical Center
- Shore Health System
- Southern Maryland Hospital
- Suburban Hospital
- University of Maryland Medical System
- Washington County Health System, Inc.

The remainder of this document provides a summary of the written comments received on the policy options identified in the White Paper: (A) Need Projection Policies; (B) Quality of Care Policies; (C) Cost of Care Policies; (D) Access to Care Policies; and (E) Other Policies. A complete set of the written comments received on the White Paper may be obtained by contacting the Division of Health Resources at (410) 764-3232.

II. POLICY AND REGULATORY ISSUES IN PLANNING OPEN HEART SURGERY SERVICES: SUMMARY OF PUBLIC COMMENTS

A. Need Projection Policies

1. Definition of Planning Regions

- ◆ Option 1: Current Planning Regions
- ◆ Option 2: Redefine the Metropolitan Washington and Baltimore Regions Consistent with Federal Designations
- ◆ Option 3: Redefine the Metropolitan Washington and Baltimore Regions Consistent with Federal Designations (Exclude Out-of-State Areas)

● **Adventist HealthCare, Inc.** supports the existing State Health Plan definition of the Washington Metropolitan Region for purposes of planning for these specialized services. Retaining the current planning regions will continue to assure that the need methodology is accurate, and properly accounts for the migration of Maryland residents, regardless of whether or not that migration crosses State lines. The rationale for selecting the four planning regions found in the current SHP is that each region selected has an adequate population base to support OHS programs whose success depends greatly on achieving high patient volumes. Because OHS services are considered tertiary care services and highly specialized, the current planning regions embrace large areas and populations. The population of the smallest region, Eastern Shore, was over 350,000 in 1998. The Eastern Shore has one OHS program. The next largest region, Western Maryland, has nearly 400,000 residents and its CON-approved OHS program is expected to become operational before the end of this year. For the other two regions, Metropolitan Baltimore and Metropolitan Washington, there are five and six OHS programs respectively serving almost 2.4 million residents each.... Over 90 percent of the residents of the Metropolitan Washington and Metropolitan Baltimore obtained OHS at hospitals located in their respective region. For the residents of the two non-Metropolitan regions, significant out-migration has occurred, but should be significantly reduced upon commencement of the newly approved CON program in Western Maryland.... There is no reason to believe that changing the regions to omit the population of Washington, D.C. would improve the need projections. To be consistent, the City of Baltimore would have to be excluded from the Metropolitan Baltimore region in order for the District of Columbia to be excluded from the Metropolitan Washington region under this option. This option as proposed does not exclude the Baltimore City population or the Baltimore City OHS programs from the Metropolitan Baltimore region, but does exclude the District of Columbia population and D.C. OHS programs from the Metropolitan Washington region. In both cases, patient in-migration to the urban centers is significant. To ignore this patient migration within one metropolitan region and not another is arbitrary and will inevitably produce an inaccurate need forecast in the Metropolitan Washington region.

•**Anne Arundel Medical Center** agrees entirely with the White Paper comment that OHS and PTCA are no longer “highly specialized, tertiary services requiring regionalization” and should be treated in the same manner as other services, except for the addition of quality standards. The White Paper discusses several options of planning regions, including the wisdom of continuing to consider out of state providers as part of the regions. However, the White Paper does not discuss the need for dividing the state into four regions in the first place. The regionalization concept acts to perpetuate existing provider monopolies, and should be replaced by a more focused view. This is particularly true in Anne Arundel County’s case. Although placed in the Central Maryland region, Anne Arundel County is not in fact part of the greater Baltimore market. Patients from Anne Arundel County in need for OHS services use providers in the Baltimore and Washington areas for one simple reason—they have no choice. The health care and access needs of patients in Anne Arundel County and in the areas of Queen Anne’s County and southern Maryland that are served by AAMC are not the same as the problems faced by the residents of Baltimore or D.C. areas. They should be viewed on their own terms.

•**Frederick Memorial Hospital** notes that the hospital is in the Western Maryland region. All of the options would allocate 45 percent of the patients from Western Maryland to Western Maryland. This is inconsistent with historical data, reflecting the fact that the absence of any program in western Maryland required the out-migration of 100 percent of patients needing OHS or PTCA. The White Paper also notes the approval of a new OHS program, not yet opened, in Cumberland. The White Paper should also note that an OHS program in Cumberland is simply not relevant in discussing the health care needs of Frederick County residents. Cumberland is significantly less accessible to Frederick than either the Washington or Baltimore areas. A program in the far west of the state can not meet the needs of Frederick County residents. The geography and road patterns of the counties in western Maryland should be reflected by the Plan, which should look at the needs of each county individually.

•**Holy Cross Hospital** recommendation: Option 1, Current Planning Regions should be amended to better reflect choices of Eastern Shore residents. Planning regions (markets) should largely be based upon the choices residents make, unless there is good reason to believe those choices are skewed due to lack of options. While Option 3 would help Holy Cross Hospital, we believe that one hospital in the District, the Washington Hospital Center, is a meaningful choice of care for many residents of the Maryland suburbs of the District. Ignoring WHC as a meaningful choice in this market makes no sense and duplicating all of the WHC’s capacity would not reflect a reasoned approach to balancing size and choice. Option 2, the use of Federal market areas, which would add all of Northern Virginia to the planning region, is inappropriate. The providers in Northern Virginia do not represent meaningful choice to suburban Maryland residents, and would be used even less if there were additional closer choices.... We recommend leaving Frederick County in the Western Maryland area where a new service has just been approved.... While Option 1 is closest to that dictated by our overall policy, which requires examination of choices being made in the market place, Holy Cross Hospital notes that the current markets do not best reflect such choices for residents of several Eastern Shore counties. Residents of three counties on the Eastern Shore, during the past three years, never chose the Eastern Shore provider and residents of two other Eastern Shore counties almost never chose the Eastern Shore providers. As a result of patterns of choice, given adequate current options, we

recommend that Caroline, Cecil, Kent, and Talbot Counties be added to Metropolitan Baltimore and that Queen Anne's be added to Metropolitan Washington. We do not recommend moving any Western Maryland county for the reason given for not moving Frederick County to our market area. Since residents of all other Maryland counties choose most often to have their OHS in their current planning area, we recommend no other changes.

•**Johns Hopkins Medicine** believes that the Commission should review the D.C. region and its role in the planning process. The metropolitan Washington, D.C. region does not enjoy the same program balance in market share as that of metropolitan Baltimore. Patients in the Maryland suburbs of D.C. have little choice when selecting care for cardiovascular surgery. Although there are 6 programs, four of those programs do not perform minimum surgical volumes consistent with better outcomes. This lack of competition translates into a 75 percent market share for the Washington Hospital Center. In the last year, the Washington Hospital Center physician group has taken over the cardiovascular programs at both Washington Adventist Hospital and Georgetown University Hospital. This group currently performs 95 percent of the metropolitan D.C. cardiovascular surgery. Without choice and competition, the State of Maryland and its residents are placed in a vulnerable situation. The Commission has no jurisdiction over the metropolitan Washington, D.C. hospitals for either quality of care or pricing. The State of Maryland pays many millions of dollars to hospitals in the District of Columbia for the cardiovascular care of Maryland residents who are covered under Maryland entitlement programs. This is revenue that could remain in the State of Maryland if Maryland residents in the metropolitan Washington planning region had more than one viable option for cardiovascular care in Maryland hospitals.

•**LifeBridge Health, Inc.** believes that the State should continue to foster the concept of regionalization by maintaining the current four regional service areas as defined in Option 1 of the White Paper. Open-heart surgery is currently regulated on a regional rather than a jurisdictional basis for a reason: the basic elements of the system are scarce resources. Moreover, as stated in the White Paper, for highly specialized services, a larger population basis is necessary to ensure that programs have adequate caseloads.... The current four planning regions reflect actual service areas, as well as historical physician referral and patient migration patterns and therefore accomplish the State's goal of ensuring availability of open heart surgical services to all residents of Maryland.

•**MedStar Health** believes that policy options that would significantly change the current planning region by excluding District of Columbia capacity from the need methodology for cardiac services would reverse longstanding policies of the region which looks at the Washington Metropolitan area as a single market area. This policy reversal for specialized care services could set a precedent for excluding the consideration of Washington, D.C. capacity for a number of other health care services and lead to expensive expansion of health care services simply because those services are not within the boundaries of the state of Maryland. We urge you to consider carefully a change to the current planning regions.

•Comments from the **Montgomery County Commission on Health** indicated that under current circumstances, the County is unable to provide open heart surgery and associated primary and secondary prevention programs together as its residents must disproportionately travel to the

District of Columbia for heart surgery (with the exception of Washington Adventist Hospital) where hospitals are not subject to the same regulatory requirements as in the County. The Montgomery County Commission recognizes the open heart surgery capacity in the District, but demand exists for open heart surgery located in Montgomery County.

- Due to our preference for a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** opposes the regionalization of cardiac care. St. Agnes agrees that recent clinical advances and the resulting proliferation of OHS and angioplasty procedures since the advent of the SHP no longer make cardiac care a “highly specialized, tertiary service requiring regionalization”. All of the regional grouping options discussed represent an artificially constrained market which are not based on population migration factors of work, commerce, or recreation. The regional approach forces patients out of their natural community of providers and physicians for a service that is so routinely performed it can no longer wear the label of “specialized tertiary care”. Without CON constraints, natural patient migration would be allowed to occur based on quality care and market dynamics.

- The joint comments submitted by **St. Joseph Medical Center, LifeBridge Health, MedStar Health, and Peninsula Regional Medical Center** supported continuing to utilize a regional planning process that includes the District of Columbia. The four planning regions used in the current State Health Plan properly reflect the naturally occurring geographic markets for healthcare as well as historical physician referral and patient migration patterns. The regionalized planning approach for specialized services is more important than ever during this labor shortage and limited supply of specialized personnel.

- Shore Health System** fully endorses Option 1 consistent with the current State Health Plan. Shore Health System has invested heavily into providing medical care services in Queen Anne’s County with diagnostic centers in Stevensville and Centreville. Memorial Hospital of Easton represents the preferred institution for cardiac services by Queen Anne’s County residents. Further, Anne Arundel and North Arundel do not represent any advantages in treatment options for cardiac treatment above those available at Memorial Hospital. While more sophisticated services are available in Metropolitan Baltimore, it would be unconscionable to transport an emergency cardiac patient from Queen Anne’s County to Baltimore for treatment. Additionally, for future planning purposes consideration should be given for the migration of populations of Delaware who currently utilize Shore Health System’s hospitals for cardiac care.

- The **Southern Maryland Hospital** believes that overall the current planning regions reflect actual patient utilization patterns fairly well. The inclusion of the District of Columbia in the Washington region in some fashion is appropriate, because District hospitals (in particular, Washington Hospital Center) are the major cardiac surgery resources for Maryland patients in the Washington region. However, the dominance of District hospitals in cardiac care presents major access issues for Maryland patients, particularly in light of the growing importance of angioplasty as a critically time-sensitive treatment for heart-attack victims. The best solution would be for the Commission to use a judgmental migration factor for Maryland patients traveling to District hospitals that strikes a balance between local access and regionalization of this service. There is ample precedent for such a policy. The current version of the State Health Plan uses a judgmental migration factor for Western Maryland that reflects a policy that 45

percent of the patients should be treated locally, whereas currently they are treated elsewhere. In the 1990 State Health Plan chapter on cardiac surgery, the existing migration pattern from the Baltimore region to the Washington region was deemed excessive, and a higher Baltimore retention rate was used in the need projections in order to encourage local access to cardiac services in Baltimore. Specifically, COMAR 10.24.17F94)(e) allocated 85 percent of the projected number of cases for residents of the metropolitan Baltimore area to service providers within the Baltimore area, and allocated the remaining 15 percent to the metropolitan Washington area. As a result of that policy, CONs for new programs in the Baltimore area were approved, and the actual Baltimore-area retention rate increased to meet the Commission's goal... the solution is to strike a balance, or compromise, between the two extremes of not taking District capacity into account at all and taking it into account in such a way that it precludes local hospitals from developing their own cardiac surgery and angioplasty programs (which is the effect of the current SHP methodology). We have suggested such a compromise: Continue to include District hospitals, but allocate at least fifty percent of the projected Maryland utilization to Maryland hospitals.

•**Suburban Hospital** supports the approach to regionalization set forth in the 1997 Open Heart Surgery Section. The addition of jurisdictions in Virginia and West Virginia to the D.C. Metropolitan Region, as suggested by Option 2 is illogical since D.C. and Maryland residents do not seek cardiac surgical in those jurisdictions.

•**The University of Maryland Medical Center** agrees with the premise articulated in the White Paper that current planning regions reflect naturally occurring geographic markets. Patients routinely cross jurisdictional boundaries for care, particularly for highly specialized services. UMMC believes that this premise holds true even for the Metropolitan D.C. area. To exclude Washington, D.C. and its cardiac surgery programs from the planning process would, in effect, suggest that some sort of "fire wall" exists between the State of Maryland and the District. This, we know, is not true and many Marylanders travel into the District for cardiac care.

•**Washington County Health System, Inc.** believes that a more accurate representation would be the combination of Frederick and Washington counties as a separate region. This would more accurately reflect patient migration for a service such as open-heart surgery. Mountains geographically separate Allegany and Garrett Counties. Residents of Washington and Frederick counties will not travel west but also are not part of the D.C. metropolitan area.... We believe that need determination is better reflected in a planning region, which would combine Washington and Frederick counties, and not to separate the counties and place Frederick in the D.C. metropolitan area.

2. Length of Planning Horizon

◆ **Option 1: Three-Year Planning Horizon**

◆ **Option 2: Five-Year Planning Horizon**

• **Adventist HealthCare, Inc.** supports the existing SHP three-year planning horizon as recommended by the Technical Advisory Committee. If a new trend in utilization of OHS is sustained for the next three years, the forecast of projected need will remain accurate. If a new trend is revealed, or the expert clinical opinion of the Technical Advisory Committee is revised, a new forecast can be generated for Commission consideration. Adventist HealthCare recommends that the Commission provide the public with the most responsive methodology possible in order to address the dynamic changes occurring in the technology and utilization of these specialized services. The alternative option would extend the current SHP horizon for an additional two years. The additional two years would postpone the next update of the Plan, and preclude the consideration of more recent developments in the technology of medical and surgical treatment of heart disease, and possible needed revisions to the need projection methodology. There is no reason to believe that alternative would improve the projection; indeed, it would likely worsen the projections.

• **Anne Arundel Medical Center** agrees that if CON for OHS is to continue, the shortest possible time frame for a plan should be used. The 5-year time frame is unacceptable.

• **Frederick Memorial Hospital** agrees that if CON for OHS is to continue, the shortest possible time frame for a plan should be used. The 5-year time horizon is unacceptable.

• **Greater Baltimore Medical Center** believes that there is no question that the 3-year time horizon option is necessary, to the extent CON is necessary at all. The 5-year time horizon is simply too slow to permit the State to keep up with advances in medical care.

• **Holy Cross Hospital** recommendation: Option 2, Five-Year Planning Horizon. Balancing the advantages of size and choice requires using a time frame that relates to the likely size of the market at the time a potential new entrant should attain relative maturity. In the past, that has been assumed to be three years, and Holy Cross believes three years is reasonable. It is currently mid-2000. The modified SHP probably will not be adopted until early 2001 and even with an expedited CON proceeding, no new service is likely to be up and running until 2002. Thus, Option 1 would force an applicant to project size in 2004 based upon a market projection for 2002. Option 2 allows the Commission to reasonably assess whether any new proposed program will attain reasonable size as well as evaluate the likely impact on existing programs when the new program is mature.

• **Johns Hopkins Medicine** supports the current 3-year planning horizon because rapid technologic changes requires ability to maintain flexibility.

•The **Montgomery County Commission on Health** believes that the planning horizon should not exceed three years, as outlined in Option 1.

•In lieu of a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** supports the use of a shorter, 3-year planning horizon that would allow more frequent updates of the SHP to integrate latest clinical standards.

•Given the magnitude of advances in the provision of cardiac care services brought about by rapid changes in technology, **Shore Health System** endorses Option 1, a continuation of the Commission's three-year planning horizon.

•**Southern Maryland Hospital Center** believes that a three-year planning horizon is insufficient to allow time for revising the State Health Plan, conducting any appropriate CON reviews, and implementation of any approved programs in sufficient time to meet the projected need. The problems with a three-year planning horizon are illustrated by the current situation: The latest projections in the current plan are for 1999, and it will be late this year or early next year before any new need projections can be adopted. We believe that a five-year planning horizon would be the better option of the two. The discussion in the White Paper contains what we believe to be a fallacy: "On the other hand, this longer planning horizon could potentially make it more difficult to adequately consider emerging trends in the management and treatment of coronary heart disease". This statement assumes that the Commission would be unable to revise or update the Plan section prior to the expiration of the five-year planning horizon. This is not the case. The Commission would be free to consider revisions at any time that it believed appropriate. We also believe that the Commission should consider a third option, particularly in conjunction with the use of a five-year planning horizon: Update the need projections annually with new data. This would represent a compromise position, because the underlying need methodology would remain the same, but the need projections themselves would be kept current with the latest available information. Unlike a change in the need methodology, such annual updates could be accomplished without any amendment to the State Health Plan, so long as the new Plan chapter provides for those updates.

•**Suburban Hospital** supports the current three-year horizon set forth in the 1997 OHS Section.

•The **University of Maryland Medical Center** agrees with the planning horizon set forth in the current State Health Plan. The standard of care for cardiac services is rapidly changing-as new research is published and advanced technologies become more widely used. For this reason, we believe it is prudent to maintain a planning horizon of three years.

•**Washington County Health System, Inc.** believes that the need projections for open heart surgery planning should be a shorter three-year planning horizon (Option 1) due to the need of the Commission to be responsive to the changes within the medical field. A shorter planning horizon would allow the Commission to not only monitor the trends in utilization of cardiac surgeries, but to be able to react more quickly to changes that may occur in the delivery of medical care.

3. Use Rate Assumptions in Projecting Future Cases

- ◆ **Option 1: 1997-1999 Trended, Regional Use Rates (Current Methodology)**
- ◆ **Option 2: 1997-1999 Average Regional Use Rates**
- ◆ **Option 3: 1997-1999 Average Statewide Use Rates**
- ◆ **Option 4: Constant Base Year (1999) Regional Use Rates**

•The current SHP projections are based on regional use rates. **Adventist HealthCare, Inc.** has always advocated for projections based upon regional use rates because there has been a measurable disparity in use rates among the residents of the planning regions....The need methodology is currently very accurate. There is no reason to believe that projections based upon alternative use rates would be more accurate. Therefore, there is no reason to change the use rates in the SHP. Moreover, regardless of which option is selected, the number of OHS patients forecasted to need OHS in 2002 is not significantly different than the actual number of cases reported in 1999. For this reason, there is also no impetus to change.... Finally, because use rates of OHS have leveled off since 1996, any realistic assumption of future need should reflect this trend. Regardless of which option is selected, the future unmet need for OHS in the two metropolitan regions is not likely to be sufficient to justify the approval of another OHS program in either region.

•**Anne Arundel Medical Center** believes that use rate assumptions are part of a traditional approach. Differences in use rates can be due to many reasons, even when age-adjusted use rates are used. The differences in use rates for OHS between regions is not explained in the White Paper, and is doubtless not known. While AAMC does not support the regional approach used in the White Paper, AAMC believes that it would defy logic to design a “regional” system and not use regional use rates. Therefore, if need projections are going to be used at all, Option 2—average regional use rates—is the preferred and logical choice. Statewide use rates would ignore the evident differences between different areas of the state, and would distort the need calculation.

•**Dimensions Healthcare System** believes that Option 2 would be the preferred method for projecting use rates. Option 3, the use of statewide use rates, is inadequate because it fails to take into consideration substantial regional variations in use rates based on demographics, geography, practice preferences and other factors. Option 4, the use of the 1999 use rate, is problematic if 1999 were to prove to be an aberration for whatever reason.... Option 2 is the option most likely to generate valid and reliable use rate data for the calculation of need, and Option 4, the least likely.

•**Greater Baltimore Medical Center** supports the use of Option 2 – average regional use rates. The data reveals that there are differences in use rates, but not the reasons for the differences. Regional use rates make the most sense as long as “regional” need is being

projected. The state's regions are different, and a state wide use rate would act as a boon to some regions and a detriment to others.

- Holy Cross Hospital** recommendation: Most recent (corrected) statewide age specific use rates (i.e., 1999) updated for population change. Holy Cross Hospital believes that balancing the advantages of size and choice requires making the most realistic decision about the size (need) of any particular region. Holy Cross has reviewed data and concludes that the above recommendation better projects use than any option provided by staff, even though it slightly under projects use due to the small increase in use rates. The use rates in the tables are all based upon the assumption that GW University Hospital performed no OHS services in 1999, when, in fact, GWU simply did not report data. The Commission must adopt a method for estimating the volume at non-reporting hospitals which is much more reasonable and does not, in effect, reward a hospital for not reporting. Holy Cross recommends using the greatest number of OHS cases in the last three reported years for any non-reporting District hospital. Based on our review of the data, Option 1 corrected for the omission of GWU data, would be our second choice.

- Johns Hopkins Medicine** supports the use of trended, regional use rates.

- LifeBridge Health, Inc.** believes that the State should use 1999 use rate statistics as the baseline for projecting need, as set out in Option 4 of the White Paper. Recent figures document that open heart surgery use rates have begun to decline or stabilize among Maryland residents, lending further support that adequate capacity (if not excess capacity) exists in Maryland. The total number of open heart surgery cases per 100,000 residents age 15 and over has declined from 183 in 1997 to 178.6 in 1999. In addition, clinical practice trends argue for a conservative approach towards measuring need. Cardiovascular disease can be treated medically, surgically or via transcatheter techniques, and important changes occurring in clinical practice are likely to impact caseload in each of these areas. Clearly, these changes are highly relevant to forecasting use rates and resource requirements as they related to need.... Industry reports forecast a decline in the use rates and in the absolute numbers of open-heart surgery cases, even amidst the dramatic growth of minimally invasive cardiac surgery.... The key factors influencing the decline in use rates and absolute numbers of procedures are as follows: success of stenting and new antirestenosis treatments; and medical management approaches.... Clearly, there remains a great deal of study to be done to evaluate these new procedures and to establish the long-term benefits of drug therapy. At the same time, the rapidly-developing technology for less invasive cath lab procedures and the positive results being documented by some of the new drug therapies all argue for a conservative approach towards determining need for open heart surgery.

- In lieu of a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** supports Option 2 (average regional use rates) as the preferred alternative. As demonstrated in the data represented in the White Paper, there are significant regional differences in utilization of OHS and angioplasty services. It would be illogical to design a regional system and not utilize regional use rates to project volumes of procedures.

- The joint comments submitted by **St. Joseph Medical Center, LifeBridge Health, MedStar Health, and Peninsula Regional Medical Center** supported use of 1999 regional use rate statistics as the baseline for projecting need (Option 4). Given recent changes in practice

patterns and documented changes in use rates, the most currently available statistics should be adopted to establish a new baseline.

•**Southern Maryland Hospital Center** believes that, of the four options outlined in the White Paper, that Option 3 (Average Statewide Use Rates) is the best. Note that these use rates could, in addition, be trended in the same way in which regional use rates are trended in the current Plan. Trending has become less important than it was in the past, because the steep rate of increase in the use rates for cardiac surgery appears to have leveled off. While it is true that some of the differences in use rates between the various regions in Maryland may be attributable to differences in population characteristics (other than age distribution) and physician practice patterns, we also believe that availability and access have influenced these use rates. In particular, we believe that the higher use rate in the metropolitan Baltimore area as compared to the metropolitan Washington area is attributable, in part, to the greater availability and wider dispersal of cardiac surgery services in the metropolitan Baltimore area. It may also be significant that the dominant provider of cardiac surgery services in the metropolitan Washington area is located in the District of Columbia and is not subject to regulation by HSCRC. Thus, there has been no assurance of cost-effectiveness or of financial access to these services by way of the HSCRC's allowance for uncompensated care. A compromise position that is not considered in the White Paper would be to use an average of the regional use rate and the statewide use rate for each region. While inexact, this would strike a balance between regional differences attributable to population characteristics and differences in utilization attributable to access and cost.

•**Suburban Hospital** proposes a statewide use rate without trending in lieu of the regional use rate/regional trending approach in the 1997 OHS Section. Suburban believes that the statewide use rate, the approach followed in the 1990 OHS section, is more predictive of future utilization.

•**The University of Maryland Medical Center** indicated that the current use rate methodology appears to have over projected the actual number of open heart surgery cases throughout the State in 1999. In fact, the total number of open heart surgery cases performed in the State has been somewhat constant in recent years influenced by such factors as demand for service, access, managed care, reimbursement, changes in medical practice, and technology. Given these dynamics, it does not seem appropriate for new methodologies to be adopted that would project even higher use rates going forward. The White Paper provided no option to remedy current shortcomings in use rate assumptions so that future projections would not be overstated by as much as 21 percent.

4. Measurement of Program Capacity

◆ **Option 1: Capacity Based on Physical Operating Room Space**

◆ **Option 2: Capacity Based on Actual Service Utilization**

• **Adventist HealthCare, Inc.** believes that there is a third alternative that was discussed by the TAC. The third alternative is to measure program capacity by examining dedicated resources which would include the number of dedicated operating rooms as well as other dedicated program resources to obtain an accurate measure of capacity. Adventist HealthCare supports this third alternative. For every other inpatient hospital service planned and regulated by the Commission, some measure of physical capacity is used to fix the allocation of resources needed to address future patients needs. In most cases that resource allocation is by licensed beds. Implicit in this measure of bed capacity is not simply the piece of furniture that is required to accommodate the hospitalized patient overnight, but rather the entire infrastructure necessary to support that patient in the institution: the patient rooms, the ancillary services, the nursing staff, and so on. The TAC recognized that the measure of operating room capacity did not explicitly measure the balance of the hospital's infrastructure when it assigned to each OHS program the capacity to perform 500 OHS cases per dedicated operating room per year. For that reason, the TAC recommended that the capacity measure be expanded to include the other resources needed to care for the OHS patient, including staff availability, in the existing programs....The TAC did not recommend that operating rooms be abandoned as a measure of capacity; it recommended that the measurement be refined to consider other factors. That is the option Adventist HealthCare supports.... If capacity is to be measured by historical performance, it should not be measured by aggregate annual performance. Such an aggregate measure overlooks the peaks and valleys of daily performance. The measure should examine the daily performance of dedicated OHS resources.... The alternative measure of capacity in the White Paper—limiting capacity to what has been done in the past—is not truly a measure of capacity. It shows what was done without the vision of what could have been done. This approach is fundamentally flawed in concept. To measure the capacity of existing OHS programs to accommodate future patients on the basis of past utilization is not different than measuring the capacity of schools to accommodate future enrollment on the basis of past attendance. What is missing, of course, is some factor which measures how many students each school can enroll within its physical constraints.... Adventist HealthCare believes that measuring cardiac surgery program capacity should involve an examination of what resources dedicated in an open heart surgery program are capable of performing. While there may be room to debate exactly which measure of operating room space more accurately measures the additional patient demand which can be accommodated in any particular hospital's program, there is no doubt that a program's capacity is best measured by its current dedicated resources rather than past performance. While past performance may be an indication of what can be done in the future, it is at best an indication. What the program can perform is a function of dedicated resources.

•**Anne Arundel Medical Center** believes that the issue in OHS in Maryland has not been the number of predicted cases. The contention has always been over the “net need”—the artificial number derived from subtracting existing capacity from the total predicted need to see if 200, or 350 “new” cases existed. The exercise is, of course, predicated on the belief that access should be limited, not by the number of procedures but by the number of providers. There is sufficient “need” to support several additional programs. That need, representing improved access, is only eliminated if “capacity” is measured in terms that existing providers can control. Both suggested options are within the control of existing providers, and it will be no surprise that “capacity” swallows need. Option 1 uses dedicated operating room capacity at existing providers as a starting point, and then multiplies it by an “optimal” operating room use rate. This option picks the least important element of the cardiac care continuum and uses it to measure capacity. The goals of health planning are access, quality, and cost. The number of dedicated operating rooms has virtually nothing to do with any of them. It is subject to manipulation by the “haves”. It ignores the issue of angioplasty altogether—angioplasty is linked to OHS under the Plan based on the assumption that an OR should be available when an angioplasty is underway. If so, shouldn’t the number of angioplasties be added to the number of OHS procedures to determine if there is sufficient “capacity”. The Plan does not suggest how OR capacity and angioplasty should be linked.... The White Paper offers a range of between 5,250-7,500 OHS capacity using various case/OR numbers in Central Maryland. Not surprisingly, this “capacity” is greater than the projected need under any of the four need options. Option 2 would measure each existing program’s capacity as the greater of its actual utilization or 350-cases/year.... Option 2 first requires the patient to go to an existing program for care, and then measures capacity by the number of patients treated at those existing programs. As long as the “haves” keep their collective doors open, there can never be any “need” because the aggregate capacity of the “haves” will always increase to consume any projected need. This is made worse if one of the program volumes are captured by another “have”, because Option 2 would count the capacity of successful programs without any cap, and inflate the capacity of those that are not successful as if they treated 350 cases/year. AAMC suggests that each program should be measured by (1) the lower of its actual utilization or the utilization standard adopted under the quality of care section of the plan or (2) the lower of its actual utilization or a reasonable cap on the number of procedures that will be counted at any one hospital whether that volume cap is 350 or 500 cases or some lower number justified by the literature. Measuring capacity of existing volumes may make sense in a free market. It does not make sense in a market in which most of the hospitals are forbidden to provide care.... AAMC agrees that there is a correlation between a reasonable level of procedures and better outcomes, but there is no evidence that mega-programs produce better outcomes than smaller, reasonably sized, programs. There are access advantages in having additional programs—particularly in large hospitals located in counties without an OHS provider—with reasonable volumes as opposed to a smaller number of mega-programs. Imposing a reasonable limit on the number of procedures counted from any one center—solely for the purpose of estimating capacity under the Plan—balances the need for access and maintaining quality. It will also provide competition to lower prices thereby meeting all three prongs of health planning—increasing access, maintaining quality, and promoting cost efficiency.

•**Dimensions Healthcare System** believes that operating room capacity provides the most realistic and most easily applied standard... two cases per operating room per day is a

reasonable measure of capacity. Furthermore, the factors mentioned in the Technical Advisory Committee's recommendation 6.2 should be considered along with, rather than in lieu of, operating room capacity.

- The White Paper discusses only two options. Neither is acceptable to **Greater Baltimore Medical Center**. With respect to Option 1 (current plan), GBMC agrees with the White Paper that use of dedicated operating rooms is irrelevant to patient care and subject to manipulation by the existing providers. It is not an effective measure of anything other than the number of operating rooms dedicated to open heart surgery, and it ignores the issue of angioplasty. Operating rooms are relatively inexpensive, because the expense is largely in the operating room teams and in the recovery process. The act of dedicating an O/R to open-heart surgery is a virtually meaningless measure of capacity, and should be discarded. Option 2 would measure each existing program's capacity as the greater of (i) actual utilization, or (ii) 350-cases/year. This proposed option serves only to protect the OHS "franchises" under the CON program. The existing regional plan forces patients to go to an existing program for care. If capacity is then measured by the number of patients treated at existing programs, without any cap on that capacity, capacity will always equal need. This option is supportable only if it is accepted as necessary to limit the number of hospitals permitted to provide OHS care. Under this approach, as long as the "haves" keep their collective doors open, there will never be any "need" in Central Maryland because the aggregate capacity of the "haves" will always increase to consume any projected need. Option 2 would count the capacity of successful programs without any cap, and inflate the capacity of those that are not successful as if they were minimally successful. It is effective to protect the existing providers from competition, but serves no other purpose. GBMC believes that each program should be measured by the lower of its actual utilization or the utilization standard adopted under quality of care standards discussed below. The use of numerical standards alone as absolutes may be inappropriate, but they can establish a base line for capacity.

- Holy Cross Hospital** recommendation: Capacity should be defined based upon a mix of actual service utilization (as proposed in Option 2) subject to a market share limit that balances the advantages of size with the advantages of choice. Specifically, Holy Cross Hospital proposes the following policy definition of capacity: (a) For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence; (b) For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market-based constraint; and (c) The capacity of any program is defined as limited to the higher of 800 cases or 40 percent of the projected gross need for the hospital's planning area. The decision you make on this policy issue is critical. The reason the current plan finds no net need in our market is solely based upon the current definition of capacity. Holy Cross Hospital's proposal has the following characteristics: protects new entrants, by giving them a fair change to attain a reasonable efficient size; ensures capacity is based on procedures done, not the number of OR's. It also permits some of the projected growth in the market to go to new entrants, so that additional meaningful choice is possible when the size of the market supports.... It balances the advantages of size and choice, by saying that it is reasonable to have one provider in small markets, defined as a market projected to have less than 1000 cases. It is not acceptable, however, to maintain excessive market share, and thereby limit meaningful choice, in large markets. The 40 percent limit avoids what is referred to in the economics literature as a

“dominant firm”. Given the inequalities of size, this definition is likely to yield the need for more than three meaningful choices in any large market. As long as the other requirements for entry are met, this is an excellent outcome for residents. Option 1, in its various sub-options, bases the capacity to perform OHS as a multiple of the number of operating rooms. This definition should fail for at least three reasons. First, given that existing providers can always add more OR’s, it effectively removes the possibility of additional choice for OHS and other important cardiac services in markets which already have existing OHS providers even when there is little meaningful choice. Second, in the Washington suburbs, Option 1 ignores the fact that much of the capacity is not meaningful to Maryland residents (as demonstrated by their historic choices). Third, it equates OHS services with operating room capacity, which are a tiny part of both the clinical services and costs associated with an OHS program. Defining OHS capacity based on OR capacity is bad public policy. The current definition of capacity, or any definition based upon OR use, will retain the status quo because it reserves any new net need for programs, many of which our citizens simply do not use. The result is, and will be, an ever growing market share for the dominant provider. Additional choice is effectively eliminated because there has been no control on the number of OHS operating rooms.... Basing net need on any of the sub-options under Option 1 will result in ever more market concentration and monopoly power at WHC, as it has during the past three years.... Defining OHS capacity based upon OR capacity is bad medical policy.... An OHS program is much, much more than operating rooms. Defining OHS capacity based upon OR capacity is bad economic policy. The capital cost discussed above under “Savings to the Community v. Investment” was the capital cost for starting an entire open heart surgery service. The capital costs of equipping and renovating an operating room, or two operating rooms for OHS are considerably less. The annual depreciation cost of renovating and equipping an operating room for open heart surgery is approximately \$50,000. Total depreciation for two OHS operating rooms is \$100,000. This is less than 1 percent of the cost of a successful open heart surgery program. Clearly, letting 1 percent of cost dictate policy decisions is not good public policy. Finally, Holy Cross Hospital notes that, had the current definition of capacity been in place earlier, neither Sinai Hospital nor Union Memorial Hospital would have been found to be needed.... In sum, Option 1 should be rejected.

•**Johns Hopkins Medicine** believes that use of OR capacity is a flawed methodology because of the ability to add OR’s and that this methodology should be eliminated.

•**LifeBridge Health, Inc.** believes that the current measure of program capacity of 500 cases per OR per year should be retained. Supplemental indicators could be used as well. The Final Report of the Technical Advisory Committee on Cardiovascular Services documented that existing hospital providers demonstrate more than adequate capacity as measured by available operating rooms. “Available program capacity” has been defined historically by the number of operating rooms, with the assumption that each operating room can reasonably serve 500 cases per year. The 1999 TAC recommendation for elimination of this benchmark as the sole measure of capacity is modified by the statement in the text of the report that the measurement should be “refined” to include additional factors such as waiting times, transportation issues, staffing, and program outcomes. We believe that the number of dedicated ORs serves as a good proxy for all of these types of measures. In fact, dedicated OR capacity generally does correspond to and include investments in specialized technology, ICU operations, surgical teams and caseload

potential, and it is easily measured. The benchmark of 500 cases per year, or 2 cases per OR per day, represents an 8-hour day, during which two 3-hour procedures can be performed allowing for “turnaround time” which essentially involves cleaning up and preparing the OR for its next procedure. All of these elements and processes contribute to the value of this measure as a proxy for “available capacity” and it should be retained.... Finally, 500 cases per OR per year is even more compelling a target as we watch case length decline. The movement towards off-pump procedures and other clinical practice trends outside the realm of open heart surgery are already causing the time per case in the OR to decline, not increase. Thus, pressure on existing OR time is declining, not increasing correspondingly. Acknowledging the TAC recommendation to consider a supplement to the existing measure of program capacity, such capacity could potentially be assessed along several dimensions to assure quality programs.... For example, a hospital could document the date and time a request for urgent surgery is received and the date and time of surgery. The relevant measure would be the percentage of referrals served within a specified period of time.... A final alternative policy would potentially limit the OR capacity of existing providers by requiring them to meet the same requirements a new applicant would have to meet to establish a new program. This requirement would effectively inhibit the ability of existing providers to continue to expand operating rooms to meet identified need, if such expansion is determined to be inappropriate, and allow new entrants an opportunity to attempt to justify a program.... While the objective measure of program capacity should be retained, capacity in the real world is impacted by the overall shortage of nursing personnel, which is even more critical in the areas implicated in the performance of open heart surgery.... Finally, with all due respect to the Commission’s ability to recognize a red herring when it sees one, the flow of patients through the emergency room has absolutely nothing to do with the capacity of the operating suite to accommodate open heart patients.

- MedStar Health** strongly believes that the operating capacity standard of 500 is appropriate and achievable in efficient high volume programs as demonstrated by our experience at the Washington Hospital Center and at other high volume programs. Perhaps the capacity standards should include other factors, the operating room availability based on the case time is a reasonable component of that capacity standard. The operating room capacity standard, whether a single measure of capacity or a component of a broader measure of capacity should not be set at the average level of actual utilization but at a level that is reasonably achievable based on “best practice”.

- The Montgomery County Commission on Health** supports the Technical Advisory Committee’s recommendation to redefine capacity to include patient outcomes, assessment of future need, staff availability, access and cost, and that this definition be incorporated in State standards.

- In lieu of a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** would recommend that each program’s capacity should be measured as the lower of its actual or the minimum utilization standard adopted under quality of care standards or alternatively, that a cap be used in measure the capacity at any hospital not to exceed 400 cases or double the ACC standard. Any cases above that number would not be counted as existing capacity. In the existing SHP, this standard, more than any other, prohibits the development of new programs. The standard is driven in part by the premise that “higher volumes, achieve

better outcomes”. While studies do indicate a correlation between the relationship of volume to quality, this is true only to a certain threshold. Volume levels beyond the “quality threshold” do not contribute to further improvements in patient outcomes. Therefore, while the statement “more is better” is true, there is no evidence to support the statement “much more, is much better”. Certainly, in some situations, much more can result in much worse. The use of the criteria standard of the greater of actual volume or 350 cases per year ensures that new programs will never be opened. There will never be any “need” because the aggregate capacity of the “haves” will always increase to consume it. This option only serves to continue the economic and competitive advantage of existing programs. It is an interesting observation that the CON system first limits the patients’ choice of provider, and then measures capacity by the number of patients treated by those existing providers. The impact of this standard is twofold. First, successful programs are virtually without a volume cap. Second, unsuccessful programs are treated as if they were minimally successful. It is St. Agnes position that a quality program should be based on more than just the total volume of procedures that are performed. We strongly urge the Commission to consider other quality standards such as time to definitive treatment, community education, community outreach, chest pain capability, patient outcomes, and other relevant criteria.

•The joint comments submitted by **St. Joseph Medical Center, LifeBridge Health, MedStar Health, and Peninsula Regional Medical Center** supported maintaining the current measure of program capacity which assumes 2.0 cases per day per operating room or 500 cases annually. “Available program capacity” has been defined historically by the number of operating rooms, with the assumption that each operating room can reasonably serve 500 cases per year. This number reflects the assumption that 2 open heart surgery cases per day per operating room --- functioning 5 days/week---is a reasonable benchmark. The 1999 TAC recommendations called for elimination of this benchmark to be replaced by capacity measures that better reflect access, quality, and service availability. In this context, we would make the following statements and recommendations: (1) the number of dedicated ORs serves as an excellent proxy for program capacity and should be maintained as the fundamental indicator with which to measure program capacity (The number of dedicated ORs does indeed serve as an excellent proxy for program capacity. Dedicated OR capacity generally does correspond to investments in specialized technology, ICU operations, surgical teams, and caseload potential. In addition, it is easily measured.); (2) the assumption that each dedicated OR can serve 500 cases per year or two cases per day per room continues to be a reasonable one, and an appropriate basis for measuring available program capacity (This working assumption was supported by the large majority of TAC members and represents only an 80 percent utilization target for each dedicated OR. We would emphasize, as well, that 2 cases per OR per day is a very reasonable target—particularly as we watch case length decline. The movement towards off-pump procedures and other clinical practice trends are already showing that time per case in the OR is declining, not increasing. Keep in mind, then, that pressure on existing OR time is declining, not increasing.); and (3) As pointed out in several minority opinions to the TAC’s final report, only 25 percent of the TAC membership voted on the recommendation to remove the measure of 2.0 cases per OR or 500 cases annually. (As stated by Dr. Donald Dembo in his minority opinion to the TAC, “it seems inconsistent that we abandon concepts of capacity numbers when we specify the minimum number of procedures that must be done annually.)

•**Shore Health System** is mute regarding both capacity options. The data provided identifies the existence of excess capacity when projected demand is compared to existing open-heart surgery operating room availability. It does not address convenient access to open heart surgery. There is a mismatch between the location of services concentrated in metropolitan areas of Baltimore and Washington and the demand or need for services in outlying areas. The open-heart programs in the metropolitan areas continue to rely heavily on referrals from surrounding areas.

•**Southern Maryland Hospital Center** believes that the use of operating room space as the definitive measure of cardiac surgery capacity is fatally flawed. Many of the problems inherent in such a measure are well summarized in the White Paper at page 21. As the White Paper recognizes, cardiac surgery is far more dependent on the availability of a highly trained team of professional health care providers than it is on the availability of an operating room. For example, a hospital might have several operating rooms available in which to perform additional cardiac surgery, but if its existing dedicated cardiac surgery team is performing the maximum number of cases which it can safely and effectively handle, the hospital will be unable to significantly expand the number of cases it performs without hiring an additional cardiac surgeon or surgeons, an additional pump technician, additional operating room nurses with cardiothoracic expertise, and additional nursing personnel to care for the patient during post-surgical recovery. Moreover, even if a hospital has the theoretical capability to perform additional cases, based on its existing staffing and physical resources, this capacity will not be of any practical benefit if the cardiac surgery program is one which has been unable to win the confidence of patients and referring physicians. Every new cardiac surgery program deserves a period of time within which to prove itself. But when a program has consistently failed to reach even the minimum volume threshold of 200 cases for ten years, it is apparent that the hospital has simply been unable to get the job done.... We believe that it would be far better to measure capacity based on actual service utilization. There is ample precedent for using actual service utilization as a measure of capacity. For example, the State Health Plan measures the capacity of existing home health providers and of existing hospice providers in terms of their historical utilization, even though those existing providers could easily serve additional patients with little or no capital expenditure.... Specifically, we recommend that capacity be measured by the highest actual annual volume ever attained by the hospital during the past three consecutive years, subject to one exception. The sole exception to that rule should be in the case of a new program that has received a CON. Since a new program has no operating history on which to base its capacity, it would be appropriate to measure the capacity of a new program by the highest volume that it projected in its CON application. However, after the program has been in existence for three years, its capacity should be measured in the same way as other existing programs.

•**Suburban Hospital** believes that the 1999 TAC got it right when it included Recommendation 6.1 in its Final Report to the Commission: *The Technical Advisory Committee recommends that the capacity benchmark used in the 1997 SHP Chapter on OHS (two cases per OR per day) be eliminated.* The 500-case per OR benchmark produces such large, unrealistic case excesses that no new program will ever be approved in Maryland.... The 500-case per OR capacity measure imposes a moratorium and protects the Hospital Center with its almost 75 percent market share from any new competition for all time.... There is no stable definition of an OR that permits certainty with this approach, even if it was otherwise advisable. Existing

programs can increase or decrease OR capacity at their whim simply by re-labeling other ORs or using operating rooms for multiple purposes. Finally, actual utilization, both in Maryland and elsewhere in the country, is nowhere near the level of two cases per day, i.e., the underpinning for the 500-per case OR standard. This is particularly telling since the 1997 TAC relied on “the experience of area programs” as its basis for supporting this notion, even though there is no Maryland data that supports this conclusory statement.... Suburban believes that existing program capacity should be measured by the highest volume achieved by each existing provider in the last three years. In addition, Suburban proposes that a 40 percent cap be assigned to the capacity of each existing program in the Baltimore and Washington regions. Use of a 40 percent cap in the methodology would recognize the dysfunctional nature of the Washington cardiac surgery market and permit development of a new OHS program there.... Inclusion of the 40 percent cap would also mean that the Commission would return to a policy of managed growth in cardiac surgery program development. All of the benefits of this approach, as experienced in the Baltimore area, would become available to Maryland residents seeking cardiac surgery in the D.C. region. While permitting controlled growth in the D.C. area, Suburban’s proposed changes, including the 40 percent cap, would not result in development of a new program in the Baltimore area in Target Year 2002.

- The **University of Maryland Medical Center** indicated that programmatic capacity is directly related to the number of operating rooms that a hospital has dedicated to open heart surgery does not reflect the many staffing and infrastructure requirements that allow an institution to perform a certain number of open heart surgical cases. Additionally, the assumption that historical volumes represent a program’s capacity, again, does not reflect the actual ability of a program.... UMMC believes that the measurement of programmatic capacity should be much more comprehensive. Capacity for program volume is tied to such things as the number of cardiac surgeons, post graduate fellows, cardiac ICU recovery beds, surgical acute care beds, OR nurses, ICU nurses, and cardiac catheterization capabilities.

- Washington County Health System, Inc.** supports the Technical Advisory Committee’s approach to examine the resources dedicated to the open-heart surgery program to determine what volume can be performed. Capacity needs to go beyond operating rooms to examine staffing and other resources.

5. Patient Migration Patterns

- ♦ **Option 1: Constant Patient Migration Patterns Between Base /Target Years**
- ♦ **Option 2: Modified Patient Migration Patterns Between Base/Target Years**

- Adventist HealthCare, Inc.** suggests that no modifications be made with respect to the patient migration patterns by either in-State or out-of-State patients who migrate to OHS programs in the four planning regions, with the exception of the patient migration assumptions already in place for Western Maryland. Until the newly-certified program for Western Maryland

commences providing services, certain assumptions which can reasonably be made concerning patient migration should continue.... For the vast majority of patients residing in the two metropolitan planning regions of the State, the area of residence and the location of the OHS hospitals where they receive care is identical. Moreover, the travel time for these patients is well within the two hour limit set forth as the standard in the current SHP.

•**Anne Arundel Medical Center** believes patient migration is driven by factors not measured in the White Paper—the artificially constrained market, and the ability of insurers to force patients into high volume preferred “have” centers. Patient migration similar to that seen for other medical surgical services would be likely to occur if the CON constraint were removed, and should be used in areas without an OHS provider in the county. Either patient migration option—assuming that patient migration will remain constant or establishing a threshold reflect the need to out-migrate created by constraining the system and insurer limitations.... Projecting the continuation of patient out-migration in an artificially constrained system merely acts to continue the “need” constraint.

•**Frederick Memorial Hospital** believes that patient migration is driven by factors not measured in the White Paper—the fact that western Maryland patients are required to go outside the region for care, and the ability of insurers to force patients into high volume centers even for routine heart care. Patient migration similar to that for other medical surgical services would be likely to occur if the CON constraint were removed, and should be used in areas without an OHS provider in the county if the need projections will be applied to PTCA as well as OHS.

•**Holy Cross Hospital** recommendation: Holy Cross recommends that applicants should have the burden of proof that migration pattern will change. Option 1, slightly modified to better project the likely change in migration patterns associated with the new program in Western Maryland, should be the base line, but it should be subject to challenge in an individual situation. This issue is largely technical in nature. Our framework suggests that the Commission would want to make the best estimate of future migration patterns. In general, we agree that the best guide is current migration patterns between the regions. However, a new program should be allowed to show how migration patterns would change. Adding a new program on the geographic edge of a region is likely to change patterns from the neighboring region, while adding a program close to an existing provider is not. Current county specific migration patterns also should inform this decision on a case by case basis.... In addition, Holy Cross believes that migration assumptions would be more accurate if made on a county by county basis, especially as it related to the anticipated changes in Western Maryland.

•**The Montgomery County Commission on Health** recommends that any hospital requesting a CON for cardiac services be required to discuss patient migration patterns in their proposal; specifically, how, and to what extent, their planned service would change current migration patterns.

•**Southern Maryland Hospital Center** strongly supports the use of what the White Paper refers to as “a threshold on out-migration for services”. In particular, we believe that it would be appropriate to modify the existing migration patterns in the metropolitan Washington

area to change the allocation of future need such that at least 50 percent of the Maryland patients in the metropolitan Washington area are projected to be served by local Maryland hospitals.

•The **University of Maryland Medical Center** believes that the use of existing migration patterns should be used in need methodologies.

B. Quality of Care Policies

1. a. Minimum and Threshold Volume Standards: Open Heart Surgery

◆**Option 1: Minimum Utilization Standard of 200 Cases Annually**

◆**Option 2: Minimum Utilization Standard of 100 Cases Annually**

◆**Option 3: Minimum Utilization Standard of 500 Cases Annually**

◆**Option 1: Threshold Utilization Standard of 350 Cases Annually**

.. **Option 2: Threshold Utilization Standard Equivalent to Minimum Utilization Standard**

.. **Option 3: Threshold Utilization Standard of 800 Cases Annually**

•**Adventist HealthCare, Inc.** believes that for the metropolitan Washington region, where sufficient access to Maryland residents has already been assured, the minimum utilization standard should be maintained at the highest level of utilization possible. As David Nash, M.D. points out in his letter of July 20, 2000 to Chairman Wilson and Executive Director Colmers, the volume-quality relationship does not cease to end at any of the three minimum volume standards proposed in the White Paper, and that the minimum level of CABG procedures could be set as high as 800 cases per year. With respect to the threshold volume standard, i.e., the level which existing programs must maintain when a new program is approved, Adventist HealthCare believes that the threshold utilization standard and the minimum volume standard should be the same. No patient should be denied the opportunity to be treated in a Center of Cardiac Excellence which offers the full range of therapeutic cardiology procedures and OHS procedures. The preservation of high volume cardiac specialty centers should be maintained.

•**Anne Arundel Medical Center** agrees that the number of procedures performed at a hospital is one factor that is determinative of quality of care, but that other quality of care indicators, including the number of procedures performed by the physicians on the hospital's medical staff, and the total number of admissions and ER visits seen by the hospital should also

be considered as part of the quality of care standards. In the absence of any consensus of a new standard, there is not a compelling reason to adopt a minimum number higher than the existing 200 case standard. AAMC agrees with Option 2 with respect to threshold standards. Adopting protective thresholds significantly higher than the minimum case number standard merely serves to protect programs that the market and patients have chosen not to use. An applicant should be required to demonstrate that it is reasonable to conclude that it will meet whatever standard of minimum volumes is adopted, without adding an additional hurdle in the form of significantly higher threshold volumes at existing providers. The purpose of the CON laws is not to protect franchise holders from competition, particularly if that protection will prevent patients from receiving an appropriate continuum of care.

•**Dimensions Healthcare System** supports Option 1, a minimum volume standard of 200 cases annually, which was recommended by the Technical Advisory Committee. Option 3 suggests a very high standard which seems to have little support in the literature. Option 2 is based on plausible current literature, and it is Dimensions' experience that a program that performs from 100-200 procedures per year can have excellent results. However, 100 cases per year present a very low threshold for a new applicant to meet. Option 1, which is the status quo, is well supported in literature and is a reasonable target for a new program to meet. For the threshold utilization standard, Dimensions favors not only Option 1, which would permit existing programs to operate at a reasonable level of quality and efficiency, but believes that there should be additional protection for programs with special missions.

•**Greater Baltimore Medical Center** agrees that the number of procedures performed at a hospital is one factor that is determinative of quality of care, but that other quality of care indicators, including the number of procedures performed by the physicians and the total cardiac care and emergency room cardiac cases at the hospital, should also be considered as a minimum standard. In the absence of consensus on a new standard, there is no compelling reason to adopt a minimum number higher than the existing 200 case standard. GBMC agrees with Option 2 with respect to threshold standards. Adopting protective thresholds significantly higher than the minimum case number standard merely serves to protect programs that the market and patients have chosen not to use. An applicant should be required to demonstrate that it is reasonable to conclude that it will meet whatever standard of minimum volumes is adopted, without adding additional requirements in the form of significantly higher threshold volumes at existing providers. The purpose of the CON laws is not to protect franchise holders from competition, particularly if that protection will prevent patients from receiving an appropriate continuum of care.

•**Holy Cross Hospital** supports Option 1. Option 3, a minimum utilization standard of 500, is well beyond the size needed for quality of care, as shown in the White Paper's discussion of Option 1. Holy Cross Hospital does not have a strong preference for 200, say vs. 150, but believes 200 is a good balance between the advantages of size and choice. The required size should not be higher than 200. For threshold utilization standard, Holy Cross Hospital supports Option 1. Option 3, a threshold utilization standard of 800, is well beyond the size needed for quality, and as Maryland data show, well beyond the level needed to provide a low cost, high quality program. It tips the scale way too far in the direction of size, over choice. Holy Cross Hospital does not have a strong preference for 350 vs. a somewhat lower number, but believes

350 is a good balance between the advantages of size and choice. The required size should not be higher than 350.

•**Johns Hopkins Medicine** believes that the volume-outcome relationship is well documented and that the current minimum and threshold standards (200 cases for new program/350 cases after three years) should be retained for cardiac surgery programs. For mature programs, the threshold should be 350 cases.

•**LifeBridge Health, Inc.** believes that the minimum volume standard should be increased to 350 in order to ensure the rapid development and achievement of high quality services of a new program. This recommendation reflects our concern that current studies investigating the relationship between volume and quality reflect outcomes only in terms of mortality. If morbidity were considered as well, we believe that patient outcomes would increase dramatically if higher volumes were required. Lifebridge Health, Inc. believes that the threshold volume standard should be increased to 500. The complexities and expense of establishing a new program require series consideration. The daunting investment in equipment, staff, and on-going training to ensure competence should be recognized and new programs should be required to show that they will not cause existing programs to fall below 500 cases per year.

•**The Montgomery County Commission on Health** supports the Technical Advisory Committee's recommendation that a minimum of 200 procedures annually be the minimum volume standard and that 350 procedures annually be the threshold utilization standard.

•In lieu of a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** supports minimum volumes of 200 cases for OHS and 200 cases for angioplasty which are consistent with ACC recommendations represented in Options 1 (OHS) and Option 2 (Angioplasty). In general, the clinical evidence is mixed and somewhat unclear regarding the causal relationships between the various independent and dependent variables in the volumes/quality equation. What is clear, is that the number of procedures alone is not, and should not be, the sole determinant of quality care. St. Agnes would strongly encourage the incorporation of other case indicators. The threshold options presented merely serve to protect the interest of existing programs, maintaining the "much more, is much better" mentality.

•**Shore Health System** endorses Option 1 (200 Open Heart Surgery Cases Annually). It seems reasonable, until research proves otherwise, that an institutional caseload of 200 open heart cases minimally remain the standard as endorsed by the American College of Cardiology. Perhaps an equally more relevant outcome statistic would be not only institutional volume but also operating physician volume. It should be noted that current out-migration of open heart surgery patients from the mid-Eastern Shore exceeds the minimum caseload of 200 cases required to establish an open heart surgery program.

•**Southern Maryland Hospital Center** believes that the most important recommendations regarding minimum caseloads for cardiac surgery are those contained in the American College of Cardiology and American Heart Association Guidelines for CABG Surgery, as referenced in the White Paper. As noted in the White Paper, the minimum utilization standard of 200 cases annually recommended in those guidelines "continues in practice to be the

most universally accepted minimum standard for open heart surgery programs”. We believe that the State Health Plan should include a minimum utilization standard of 200 cases annually.... These is no compelling reason to establish a threshold utilization standard in excess of the minimum utilization standard. The only argument with any merit which we see is to provide a “margin of error” to ensure that the minimum standard is met. But if the applicant cannot be held accountable for failing to meet even the minimum utilization standards (which is the case under the current system), any such margin of error is illusory at best. Conversely, if the regulatory system is reformed so as to provide meaningful oversight of outcomes and quality, then a major of error will be unnecessary. Either way, it serves no purpose to have a “threshold utilization standard” higher than the volume which has been established to be associated with appropriate outcomes and quality of care (200 cases per year).

•**Suburban Hospital** believes that the Commission should adopt the 1999 TAC’s recommendations that the 200-case minimum volume standard be maintained. Suburban supports the 1999 TAC’s recommendation that the existing threshold volume standard of achieving 350 cases within three years of initiation of service be maintained.

•**The University of Maryland Medical Center** supports the notion that there is a relationship between volume and outcome, with mortality being just one measure of outcome. Although consensus on a specific minimum utilization number has not been conclusively reached, the volume-outcome relationship described in various sources suggests a minimum of 500-600 cases per institution. The Medical Center would therefore support Option 3 (Minimum Utilization Standard of 500 Cases). Planning policies should be amended as more data becomes available on the volume-outcome relationship. The same rationale for utilization applies to threshold standards, where equivalency to minimum utilization standards should be supported by published validated data.

1. b. Minimum and Threshold Volume Standards: Coronary Angioplasty

♦**Option 1: Minimum Utilization Standard of 200 Cases Annually**

♦**Option 2: Minimum Utilization Standard of 400 Cases Annually**

♦**Option 1: Threshold Utilization Standard of 600 Cases Annually**

♦**Option 2: Threshold Utilization Standard Equivalent to Minimum Utilization Standard**

•**Anne Arundel Medical Center** believes that no such standard is needed, however, Option 1 is preferred over Option 2. The lower option is consistent with American College of Cardiology standards, and a higher standard is not justified. The studies that support a 400 case

number were performed before widespread use of stents and GpIIb/IIIa receptor antagonists, and therefore are of questionable ongoing validity. Moreover, it is absolutely clear that the main quality of care issue with respect to coronary angioplasty is the skill and experience of the physician in elective bases, coupled with the smallest possible presentation to balloon time in emergencies and primary angioplasty. It is difficult if not impossible for a CON program to measure either of these factors, which in fact determine the quality of coronary angioplasty. With respect to threshold standards, there is absolutely no basis in the White Paper for Option 1 other than the fact that it is higher than either proposed minimum, and therefore supports protecting the existing providers in the name of a regionalized system. The number could as easily have been 2,000 procedures. AAMC believes that quality of care standards should be meaningful and should be enforced, and should have nothing to do with protecting the economic interests of any single hospital. AAMC does not believe any argument other than protection of existing programs supports the higher threshold standard, and therefore, AAMC urges their removal from the Plan. AAMC concurs with the TAC, which found no benefit to raising the bar between the minimum and threshold standards. As noted earlier, AAMC believes it should be set at the ACC recommendation of 200 cases annually.

•**Carroll County General Hospital** supports a minimum utilization standard of 100 cases annually. In order for community hospitals to offer this service, the minimum number of cases must be lowered. Safety would be maintained because the physicians who would be performing angioplasty at a community hospital would also need to do this procedure at other hospitals to maintain the minimum standard of 75 procedures per physician. Keeping this minimum standard per physician would maintain proficiency hence ensuring quality and safety. For the threshold utilization standard, Carroll County General Hospital supports the policy direction of a more market driven approach relying on competition. The threshold utilization standard should be equivalent to the minimum utilization standard. Carroll County General Hospital also supports the viewpoint that no additional benefit it gained by having existing programs perform above minimum standards.

•**Frederick Memorial Hospital** believes that the Commission should explore different standards for sole community hospitals to reflect their unique circumstances, at least with respect to PTCA. Frederick Memorial Hospital believes that the skill of the physician is the critical factor in PTCA, not the number of procedures performed at a facility. Frederick Memorial Hospital would encourage the use of standards for PTCA that focused on the physician and not on the hospital.

•**Greater Baltimore Medical Center** notes that there are no such thresholds in the present SHP. The White Paper addresses only elective angioplasty in this regard. It is in any event unlikely that any hospital would perform a large number of primary angioplasty alone. We can see no reason why all coronary angioplasty procedures should not be counted if a standard is adopted. GBMC believes Option 1 is preferred. American College of Cardiology standards are consistent with quality of care indicators, and a higher standard is not justified. The studies that support a 400 case number were performed before widespread use of stents and GpIIb/IIIa receptor antagonists, and therefore are questionable ongoing validity. With respect to threshold standards, GBMC believes that there is absolutely no basis in the White Paper for Option 1 other than the fact that it is higher than either proposed minimum, and therefore supports protecting the

existing providers in the name of a regionalized system. The number could as easily have been 2,000. GBMC believes that quality of care standards should be meaningful, and should be enforced. GBMC does not believe any argument other than protection of existing programs supports the higher threshold standards, and urges their removal from the Plan. GBMC concurs with the TAC, which found no benefit to raising the bar between the minimum and threshold standards.

•**Holy Cross Hospital** recommendation: no standard, but a preference. Holy Cross Hospital has not engaged a CON attorney. However, we note that the CON law refers to OHS, and not coronary angioplasty.... As such, Holy Cross Hospital questions the appropriateness of having any CON approval standards for PTCA. These could be preference standards, perhaps. Most importantly, given the limit of your authority to OHS, it would not only be bad public policy to set a threshold for PTCA that overly influenced or dictated your OHS decision, it might be illegal. Holy Cross Hospital could support a preference for any OHS provider that will perform 200 PTCA cases annually, but we do not believe any threshold utilization standard should be set. The need to increase choices for OHS in the suburban Washington market is so great, that Holy Cross Hospital can not support any threshold utilization standard for PTCA, since any standard could preclude additional choice of OHS services in order to protect current providers of coronary angiography services.

•**Johns Hopkins Medicine** believes that for angioplasty 200 cases for new programs and 400 cases after three years should be required. For mature programs, the threshold should be 400 cases.

•In lieu of a SHP based on licensure and quality of care standards, **St. Agnes HealthCare** supports minimum volumes of 200 cases for OHS and 200 cases for angioplasty which are consistent with ACC recommendations represented in Options 1 (OHS) and Options 2 (angioplasty).

•**Shore Health System** endorses Option 1 (200 Coronary Angioplasty Cases Annually). The coronary angioplasty guidelines developed by the American College of Cardiology recommend a minimum of 200 procedures annually. Is institutional volume the best predictor of outcome success? Or, particularly when relying more heavily on interventional physician competence, is operator outcome success more appropriate? A center that performs 800 angioplasty cases each year clearly exceeds the minimum standard as an institution, as compared to the center performing 200. Yet, consider on the one hand the center performing 800 cases that might have those cases performed by twelve interventional cardiologists as compared to the institution performing 200 cases annually by just two cardiologists. The operator specific volume of the 800 case center averages 66.6 cases per operating physician while the 200 case center obviously averages 100 cases per operating physician. The institutional caseload minimum are clearly met in the 800 caseload center yet each interventional cardiologist falls well below the generally accepted operator volume of a minimum of 75 cases per year.

•**Southern Maryland Hospital Center** notes that they believe that there are serious legal questions concerning the authority of the Maryland Health Care Commission to regulate coronary angioplasty services. Unlike cardiac surgery, for which there is explicit authority in the

Commission's enabling legislation, there is no specific authority granted to the Commission to regulate coronary angioplasty.... The following discussion assumes that the Commission will obtain approval from the General Assembly for appropriate amendments to its enabling legislation in order to allow it to regulate coronary angioplasty.... Similarly to the volume standards for cardiac surgery, we believe that the most important standards are the guidelines for care by the American College of Cardiology which recommend that hospitals offering coronary angioplasty perform a minimum of 200 procedures annually. As in the case of cardiac surgery, arguments could be made for lower or higher standards, but 200 procedures annually appears to be the number supported by a broad consensus of clinicians.... Just as in the case of cardiac surgery, we see no purpose in establishing a threshold utilization standard which is different from the minimum utilization standard.

- Suburban Hospital** questions the Commission's legal ability to establish minimum or threshold volumes for angioplasty. However, assuming *arguendo* that the Commission has authority to establish such standards, the co-location of angioplasty and bypass surgery ensures adequate angioplasty volume. Given the low risk of elective angioplasty with the advent of stents and new anti-platelet drugs, a program performing 200-350 open-heart surgery procedures will certainly perform 200-350 angioplasty procedures, enough to assure high quality outcomes.

- The **University of Maryland Medical Center** supports recommendations from the American College of Cardiology indicating utilization standards of 600 angioplasties per institution and 75 per operator in order to maintain competency for physicians and support staff.

2. Enforcement of Minimum Volume Standards

- **Option 1: Enforce Minimum Volume Standards for New Cardiac Surgery Programs as a Condition of CON Approval**

- **Option 2: Require Cardiac Surgery Programs Operating Below Minimum Utilization Levels to Collect and Report Outcome Data**

- Adventist HealthCare, Inc.** supports the current Plan standard requiring that new cardiac surgery programs meet minimum volume standards within 24 months of beginning operation and maintain minimum utilization levels in each subsequent year of operation.

- Anne Arundel Medical Center** believes that the current plan lacks any enforcement ability and has proven totally inadequate. If minimum standards are adopted to ensure quality of care, the State should not permit hospitals to continue offering the service at volumes below that standard. In fact, one of only three Maryland hospitals granted a CON for the OHS franchise and three of the four D.C. hospitals with OHS franchise now operate below the minimum quality of care standard.... When reality contradicts projections, something other than CON is required

to correct the situation. AAMC does not believe the Commission has the authority to do anything other than impose reporting requirements. AAMC believes those should be imposed on all OHS providers.

•**Dimensions Healthcare System** does not favor Option 1. During the entire history of the CON program in Maryland, the General Assembly has never given the Commission or its predecessors the authority to revoke or suspend the CON of an existing and operating program for violation of a condition on the CON. Quality of care enforcement is a function of the licensing authority based upon objective review of quality of care indicators. A program with acceptable quality of care has the right to continue operating regardless of the volume of surgery, and a program with quality of care problems should be sanctioned even if it has high volumes. Option 1 clearly is beyond the authority of the Commission even if done by means of a condition.

•**Greater Baltimore Medical Center** believes that hospitals should meet the standard or close down. The current plan lacks any enforcement ability and has proven totally inadequate. If minimum standards are adopted to ensure quality of care, the State should not permit hospitals to continue offering the service at volumes below that standard. In fact, one of the only three Maryland hospitals granted a CON for the OHS franchise and three of the four D.C. hospitals with the franchise now operate below the minimum quality of care standard. The Commission's predecessor certainly believed that Prince George's Hospital would meet the minimum standard when it issued the Hospital a CON after contested, batched hearings more than 10 years ago, but the standard has never been met.

•**Holy Cross Hospital** recommendation: Option 3, Require all Cardiac Surgery Programs to Collect and Report Data. Holy Cross Hospital does not believe Option 1 is either fair or legal. The Commission could, however, give a preference to a CON applicant which voluntarily makes an enforceable commitment to abandon an unsuccessful program.... We support outcome reporting, as additional information enhances choice since it increases patients' ability to make good choices among the alternative programs.

•**Johns Hopkins Medicine** would grant authority to the Commission to enforce minimums. Programs falling below minimum standards need to demonstrate outcomes equal to or better than high volume programs.

•**LifeBridge Health, Inc.** believes that programs operating below the minimum utilization standard should be subject to sanctions. In addition to the requirement set out in Option 2 for the Commission to review outcomes, we suggest that the Commission review a program's overall performance. Such review could include staffing patterns, responsiveness to requests for services, and overall patient satisfaction. Enforcement policies should be progressive, providing, for example, that after an initial ramp-up period, for any year in which the program falls below 350 procedures, that program should be required to report to the Commission on all of the indicators to be established. In addition, if in additional years the program falls below 350 procedures, the Commission could revoke the CON until such time as

the program could demonstrate ability to return to and maintain the minimum standard. Such a policy may require a change in the CON statute.

•**St. Agnes HealthCare** supports outcomes reporting as a broader component of licensure approach. The CON process has proven to be the most ineffective in this policy standard. It is interesting to note that one of three Maryland hospitals granted CON and three of the four D.C. hospitals with OHS capability currently operate significantly below the singular quality of care—200 OHS cases. The reality is that the Commission, within the boundaries of its current statutory authority, is powerless to intervene on behalf of the citizens of Maryland to enforce its own quality standard. The end result is that the Plan perpetuates the continuation of low-volume programs that the CON process would have otherwise not approved. In 1999, 4 percent of all OHS procedures were performed at facilities that did not meet the volume standard that the Plan dictates as critical to ensure quality. The inadequacy of the CON process to effectively monitor and enforce quality of care standards is one of the strongest reasons to adopt licensure as an alternative.

•**Southern Maryland Hospital Center** believes that the policy described under Option 1 is appropriate. As noted in the White Paper, it does not address the issue of existing programs operating below minimum utilization levels. For this reason, we believe that oversight of quality of care at cardiac surgery programs should be carried out under a licensure program. There is a potential problem of fairness if a new program is issued a CON with a condition of infinite duration which would render its program subject to closure for failure to meet minimum utilization levels, while existing programs not meeting minimum utilization levels would not be subject to that requirement....One way to solve this problem would be to require that the program surrender its CON only if it failed to meet minimum volume requirements for two consecutive years. Another approach would be to allow the Commission some discretion in the enforcement of the standard. A third approach would be to combine oversight with Option 2.

•Any quality review for programs not complying with minimum standards should be linked to outcome data reporting. The **University of Maryland Medical Center** recommends Option 2 in the White Paper, establishing an independent consortium to collect data and monitor outcomes.

•**Washington County Health System, Inc.** believes that enforcement of minimum volume standards should be a priority for the Commission. It has been demonstrated, and was in fact, recognized by the Technical Advisory Committee that better quality and better outcomes result from performance of a greater number of procedures. If the Commission wishes to endeavor to achieve higher quality outcomes, then the enforcement of minimum volume standards should be a requirement in order to ensure that existing programs continue to maintain higher quality and minimum threshold volume standards.

3. Outcome Data Reporting

“ Option 1: Develop Capability for Public Reporting of Outcome Data for Maryland

“ Option 2: Establish an Independent Consortium to Collect Data and Monitor Outcomes

•**Anne Arundel Medical Center** concurs in outcome reporting.

•**Greater Baltimore Medical Center** concurs in outcome reporting, but believes it should be part of a licensure process.

•**Dimensions Healthcare System** supports the establishment of an independent consortium to collect and monitor outcomes (Option 2). It is our understanding that this Option would be modeled after the experience in Minnesota and New England. This option was also recommended by the Technical Advisory Committee.

•**Holy Cross Hospital** Recommendation: Option 1 or 2. Holy Cross Hospital’s framework supports additional information as that enhances choice. That framework says to choose the mechanism that is most likely to lead to the prompt dissemination of accurate and useful information. The track record of the HCACC, as well as the successful efforts by state agencies in New York and Pennsylvania, suggest that Option 1 might be best, but there are not enough specifics to provide a strong preference between these options.

•**Johns Hopkins Medicine** strongly supports data reporting and performance improvement programming. An independent consortium for peer review and data reporting and analysis should be formed; form PI council and program.... There is more that can and should be done to improve the outcome of cardiovascular surgery in Maryland through collaboration and peer review among the existing programs. Development of an independent oversight group with participation by all existing programs, to share data and protocols, should ultimately produce results similar to the Northern New England experience. This consortium of five hospitals in Vermont, New Hampshire and Maine has decreased mortality for CABG procedures in the region from 6.5 percent expected mortality to 3.5 percent. This has been accomplished through the development of a performance improvement program, sharing protocols and experiences, and posting outcomes. There is no reason that such a consortium cannot be duplicated in Maryland.

•**The Montgomery County Commission on Health** believes that a sound performance measurement system should be developed to ensure accountability, and existing and future open heart programs should be required to submit program and outcome data.

•**Southern Maryland Hospital Center** supports the development of the capability for reporting of outcome data for cardiac care programs, either through a public agency or an independent consortium.

•The **University of Maryland Medical Center** embraces the approach of improving outcomes through collaboration and peer review. Establishing an independent consortium similar to the Northern New England Cardiovascular Disease Study Group is an effective method of providing risk adjusted feedback and continuous quality improvement....With emphasis on an evidence-based approach using national specialty group consensus regarding quality measurements, collaboration, and teamwork among current cardiac surgery providers will prove to be what is best for the citizens of Maryland.

4. Co-Location of Angioplasty and Open Heart Surgery Services

♦**Option 1: Maintain Current Policy Requiring On-Site Cardiac Surgery for Angioplasty Procedures with Limited Exemption for Primary Angioplasty**

♦**Option 2 Modify State Health Policy to Allow Primary Angioplasty in Hospitals without Cardiac Surgery Programs**

• **Adventist HealthCare, Inc.** supports the current Plan standard requiring that hospitals providing elective angioplasty must have on-site cardiac surgery back-up, and that limited exemptions from CON review be permitted for hospitals to provide primary angioplasty without on-site cardiac surgery.

•**Anne Arundel Medical Center** notes that the White Paper considers permitting hospitals to offer primary angioplasty without on-site back-up, while continuing the CON requirement for elective angioplasty. This proposal, while representing an improvement in access, is not a sufficient long-term answer to the problem of providing optimal treatment to heart patients. There are simply not enough primary angioplasty procedures at most hospitals to carry the costs associated with operating an around-the-clock service. In addition, if one accepts that there is some link between volumes and outcomes, hospitals would have to perform both elective and primary angioplasty to meet volume standards.... The issue is not, has the “haves” have framed it, whether people in need of OHS can receive surgery at any existing provider within a reasonable time frame. The issue is whether the CON ban on angioplasty and OHS helps or hinders the treatment of heart disease in the State. AAMC believes that quality of care standards applied on an individual hospital basis will provide the necessary compromise between increasing needed access and avoiding proliferation and dilution of these services.

•**Carroll County General Hospital** supports Option 2. Preliminary results of the C-PORT project indicate that primary angioplasty can be safely performed without on-site surgery.

•**Dimensions Healthcare System** strongly supports Option 1, which would essentially maintain the status quo with respect to this issue.

•**Frederick Memorial Hospital** believes that the Commission should re-examine the role of coronary angiography in sole community providers. The current SHP regulates PTCA under the open heart surgery services section, and restricts its availability to those few hospitals with on-site OHS programs and, with respect to primary angioplasty only, to hospitals participating in a research study turned registry (the C-PORT study). Frederick Memorial Hospital urges the Commission to consider whether the linkage between open-heart surgery and angioplasty is still necessary, and to explore methods that would make coronary angioplasty more accessible at sole community providers such as Frederick Memorial Hospital and to the patients they serve.

•The White Paper considers permitting hospitals to offer primary angiography without on site back up, while continuing the CON requirement for elective angiography. **Greater Baltimore Medical Center** believes that this proposal, while representing an improvement in access, is not a sufficient long-term answer to the problem of providing optimal treatment to heart patients. There are simply not enough primary angioplasty procedures to carry the costs associated with operating an around the clock service, making it not currently economical. In addition, we concur that there is some link between volumes and outcomes, and hospitals may have to perform both elective and primary angiography to meet volume standards. It is becoming increasingly clear in the literature that timely care within the first hour of symptoms is essential to the immediate survival of the patient, as well as long-term quality of life. No matter how efficient a transport system is created, there will inevitably be delays in treating these individuals who present to either facilities with only angioplasty, or facilities where angioplasty and heart surgery is not immediately available. Ultimately the delay results in suboptimal care for the patient. It is not practical to attempt to direct all such patients to those institutions that currently have interventional capabilities. Overall, the question is how best to provide additional access to primary angiography to heart attack patients – which all agree is necessary to shorten the time between arrival at the emergency department and receiving care – while ensuring quality of care. The public health issue may be clearly identified by asking these questions: (1) Will cardiac patients benefit if a few more large community medical centers that currently provide the initial treatment for significant numbers of cardiac patients are permitted to treat those patients effectively by adding a program for both angioplasty and on-site OHS, even at the risk that existing programs will do less cases per year? (2) Does the potential harm in forcing heart attack patients to face the delay, risk and added cost of forced transfer from one of the state's largest community medical centers to one of a mere handful of hospitals which hold a CON outweigh the benefit of continuing the CON ban on angioplasty in an effort to "regionalize" basic cardiac services and concentrate volumes at a few hospitals in the name of efficiency? We think the answer to both questions is a loud "Yes". The issue is not whether people in need of OHS can receive surgery at an existing provider within a reasonable time frame. The issue is whether the CON ban on angioplasty and OHS helps or hinders the treatment of heart disease in the State. We submit that quality of care standards applied on an individual hospital basis will provide the necessary compromise between increasing needed access and avoiding proliferation and dilution of the service.

•**Holy Cross Hospital** recommendation: Option 2. The C-PORT Project, in which Holy Cross Hospital is and has been a participant, has shown the efficacy of primary angioplasty.

Further, not a single non-CON regulated service, other than PTCA, has been subjected to such controls.

•**Johns Hopkins Medicine** believes that the issue of co-location of angioplasty and OHS needs further study and national organization recommendations. Johns Hopkins Medicine recommends keeping the current policy until research is complete and national organizations make recommendations. The safety and efficacy of angioplasty, with or without the presence of cardiac surgery backup, will become apparent after the research has been completed and there has been a review of the consensus of national specialty groups.

•**LifeBridge Health, Inc.** believes that the current policy requiring hospitals that provide coronary angioplasty services to have on-site cardiac surgical backup should be maintained. While cardiac catheterization labs have proliferated and procedure volume has increased substantially across the State, current State Health policy continues to restrict primary angioplasty to a limited number of hospitals.... We firmly believe that the level of risk associated with PTCA continues to warrant the presence of cardiac surgery back-up, except for sites that adhere to the C-PORT protocol. This position reflects the importance of having the available operating room but also reflects the broader skill set and experience represented by the cardiac surgical team.... Research continues to correlate high volume centers and low mortality rates, and coronary angioplasty continues to be one of the procedure categories highlighting this correlation. As recently as this spring, two major published studies demonstrated the correlation between higher volume centers and lower mortality rates for coronary angioplasty. The reality is that expanding the number of service sites in Maryland by decoupling PTCA from open heart surgery would create several low volume centers, where clinical teams would be exposed to limited case volume and provided with only limited experience.... State health planning policies should continue to encourage high volume centers for primary angioplasty.

•In lieu of licensure based on quality of care standards, **St. Agnes HealthCare** supports policy options that decouple angioplasty from OHS and ensure adequate volumes to meet quality standards. As noted in the clinical research studies..., it is a public health imperative that access to primary angioplasty be increased. This is the treatment of choice for many patients presenting with acute myocardial infarction. As we stated earlier, recent studies such as “Relationship of Symptom-Onset-to-Balloon Time and Door-to-Balloon Time With Mortality in Patients Undergoing Angioplasty for Acute Myocardial Infarction” which appeared in JAMA in July demonstrate the efficacy and safety of primary angioplasty in the prompt treatment of a significant number of heart attack patients. St. Agnes, along with other community hospitals around Maryland and the nation has successfully performed primary angioplasty procedures. Yet, the TAC continued the recommendation of requiring on-site OHS for coronary angioplasty. Insurers, cardiologists, and advisory groups also still recommend on-site OHS for elective angioplasty. The White Paper leaves open the question of permitting primary angioplasty without on-site OHS backup. However, the volume of primary angioplasty is insufficient to support the minimum volume standards of the SHP. Therefore, granting hospitals the ability to do only primary angioplasty is not a sufficient long term answer to the problem of providing optimal treatment of heart patients due to: the costs associated with operating a 24/7 service for a limited number of patients, especially under the new HSCRC case-rate methodology; the association between volumes and quality; and minimal clinical risk still associated with

performing angioplasty without on-site back up. The questions to be addressed here: Is it safer from a public health perspective to increase the timeliness of heart attack response by permitting a few more hospitals that currently receive large numbers of cardiac patients to treat those patients effectively with angioplasty/OHS, even at the risk that some existing programs will do slightly fewer cases per year? It is ethical to force heart attack patients to face damaging delays in treatment and transfers from some of the state's largest community medical centers to a center that happens to hold a CON? Are negative outcomes more likely to occur by the artificial CON prohibition on angioplasty in an effort to regionalize OHS, thereby increasing the time between arrival at an emergency room and access to all appropriate modes of treatment, or removing the artificial standards and allow a few more programs? The issue here is whether CON for angioplasty and OHS hinders or advances the treatment of heart disease. It really is a question of balance...how to best allocate scarce resources to their highest and best use, yet ensure timely, clinically appropriate, quality cardiac care for the citizens of Maryland? What policy standards are required to ensure timely access to angioplasty, ensure adequately angioplasty volumes to meet quality standards, and minimize patient risk? St. Agnes believes that the answer to all of these questions argues for additional OHS capacity in Maryland.

•The joint comments submitted by **St. Joseph Medical Center, LifeBridge Health, MedStar Health, and Peninsula Regional Medical Center** supported continuing to require cardiac surgical backup for angioplasty procedures. While cardiac catheterization labs have proliferated and procedure volume has increased substantially across the State, current State Health policy continues to restrict primary angioplasty to a limited number of hospital sites; coronary angioplasty still may be performed only in those hospitals with on-site cardiac surgery programs (with some exceptions provided for C-PORT Project participants). This was one area of consensus with the TAC members. We strongly support the position that this policy should be maintained, consistent with the following concepts. First, the American College of Cardiologists recommends on-site open heart surgery programs for hospitals that provide PTCA services. Second, the rate of complications requiring emergency surgery has declined dramatically, and it is a relatively small percentage of cases that actually require emergency surgery. At the same time, the TAC in Maryland—on two occasions—concluded that the level of risk continues to warrant the presence of cardiac surgery backup. This position reflects the importance of having the available operating room but also reflects the broader skill set and experience represented by the cardiac surgical team. For example, this team is far more experienced with some of the ancillary devices/procedures that may be required in certain cases such as inserting intra-aortic balloon pumps, a procedure that a community hospital team is unlikely to be very familiar with given the small case volume likely to be served there. Stated simply, the availability of the operating room, the readiness of a clinical surgical team AND the clinical caliber/experience of this team remain critical to delivering angioplasty with the proper skill set and appropriate back-up resources. Third, research continues to reinforce the correlation of high volume centers and low mortality rates, and coronary angioplasty continues to be one of the procedure categories highlighting this correlation. As recently as the Spring of this year, two major studies were published that demonstrated the correlation between higher volume centers and lower mortality rates for coronary angioplasty.... The evidence supporting the high volume favorable outcome correlation is compelling; consistent with this growing body of evidence, State Health Planning policies should be designed to encourage high volume centers for primary angioplasty. Current policy—that links primary angioplasty to open heart surgery programs—supports this goal of

maintaining high volume cardiac centers. The State must not risk compromising patient care standards by permitting “freestanding” angioplasty and the proliferation of low volume programs. Fourth, the current policy surrounding primary angioplasty is consistent with the regional planning approach adopted by the State for open-heart surgery. Implicit in this approach is the recognition of how costly a program investment is entailed by such programs; the current policy functions to control the number of programs and regionalize hospital investments in facilities and clinical manpower. The argument might be made that providers themselves can make their own “cost-benefit” calculation as to whether this program investment should be made. However, Maryland faces a serious labor shortage, affecting the availability of nurses and technicians. Cardiac programs cite enormous difficulty recruiting clinical staff, with some positions remaining vacant for more than 18 months. In this context, there is real danger in permitting the proliferation of specialized programs; new programs in the region would heighten the competition for specialized personnel now in short supply and would likely disrupt established clinical teams that have taken enormous time and energy to build.... Finally, some have argued that it is critical to provide patients with local, more immediate access to angioplasty at community hospitals. It has also been argued that it takes too long for patients to be transported from a community hospital to a tertiary one, whether they have need for either angioplasty or open heart surgery. It has been demonstrated that the vast majority of cardiac surgery cases are non-emergent. In addition, it has also been demonstrated that death rates are higher for patients undergoing primary angioplasty in small volume hospitals (2 deaths/100 patients). Therefore, the optimal decision would be to transport the patient. For either population, it is important to know that hospitals that do not maintain teams on site require approximately one hour to mobilize staff. In that same hour, a patient can be transported to a high volume center that would ultimately offer the patient better outcomes. The vast majority of open-heart surgery cases are not salvage or emergent, and instead are largely scheduled. For emergency angioplasty patients, the time spent waiting for a team to assemble is no different from the time it takes to transport the patient to another facility. Therefore, the difference to patients is unlikely to be felt or material.

• **Shore Health System** endorses Option 2 (Modify State Health Policy to Allow Primary Angioplasty in Hospitals without Cardiac Surgery Programs). Unequivocally, the overwhelming number of patients in Maryland who suffer heart attacks or MI’s present to community hospital emergency departments. Yet, few have the ability to perform one of the most widely accepted standards of medical intervention--primary angioplasty. Interestingly, C-PORT research could have been done at institutions that already perform primary angioplasty, however, the initial trial required randomization to thrombolytics. Yet, when given a choice, centers that perform angioplasty overwhelmingly prefer that over thrombolytics. Again recognizing two potential levels of care based upon geography. The Commission has recognized the importance of supporting this research by suspending the requirement for on site open heart surgery. Shore Health System believes that national trends, advances in technology, procedure refinements, new pharmacologic agents, documented significant reductions in the need for emergency open heart surgery following failed angioplasty, the time interval to next available OR all speak to the need to remove this standard. Virtually no institution maintains cardiac surgery OR and support staff while angioplasty is performed. With today’s cost constraints, no institution could afford this approach. Reality dictates that open heart surgery on site means “next available”. “Next

available” could mean in all practicality within two hours at a minimum or up to four hours or more.

•**Southern Maryland Hospital Center** believes that there is serious legal question as to the Commission’s authority to regulate angioplasty. This extends to the policy requiring on-site cardiac surgery backup to perform primary angioplasty. To put this simply, if the Commission has no authority to require a CON for an angioplasty program, then how can it place regulatory restrictions on the ability of a hospital to initiate angioplasty services? ... the standard of care is constantly evolving, and the success of the C-PORT trial has demonstrated that it is appropriate to perform angioplasty at least in certain situations without cardiac surgery backup.

•While recognizing that the Commission’s ability to require cardiac surgery backup as a condition for initiating PTCA may be questioned as a matter of law, **Suburban Hospital** supports the existing co-location requirement.

•The **University of Maryland Medical Center** supports the recommendations of the Technical Advisory Committee requiring on-site cardiac surgical backup for angioplasty, with the limited exception of those hospitals participating in the C-PORT protocols. However, as additional research clarifies the relationship between angioplasty outcomes and the presence of surgical backup, policy for open heart surgery and angioplasty may need to be modified.

•**Washington County Health System, Inc.** supports the co-location of angioplasty and open-heart surgery services together in that we believe that produces better quality outcomes at least in accordance with current medical practice. Future changes in practice of medicine may permit performance of angioplasty without OHS backup as well as the ability to perform minimally invasive cardiac procedures. A shorter time horizon for planning purposes in determining need would allow the Commission to better adapt its methodologies in accordance with potential changes in practice that may occur in the future.

C. Cost of Care Policies

1. Cost Effectiveness Standard

◆**Option 1: Give Preference in a Comparative Review to the Hospital with the Most Advantageous Rate Offer to the State**

◆**Option 2: Eliminate the Cost-Effectiveness Preference Standard**

•The current plan standard provides a preference in a comparative review to the hospital with the most advantageous rate offer. **Adventist HealthCare, Inc.** sees no reason to change this standard.

•**Anne Arundel Medical Center** believes cost of care standards are no longer necessary. Financial feasibility is part of the review criteria and stands on its own without the need for a SHP standard. Moreover, as the “haves” testified at length, insurers have proven that they can effectively force cost effective care, or at least not pay more than they believe is appropriate. Maryland’s rate regulation system is in the process of transformation, into a charge per case target system. That system is fully capacity of controlling the cost of OHS and angioplasty procedures within the hospital rate setting system.

•**Greater Baltimore Medical Center** believes that the cost of care standards are a residue of consolidated hearings that pitted numerous applicants for a single franchise against one another. The standards are no longer necessary. Financial feasibility is part of the review criteria and stands on its own without the need for a SHP standard. Moreover, the “have” hospitals testified at length that insurers have proven that they can effectively force cost-effective care.

•Comments from the **HSCRC** indicate that with respect to Maryland’s Medicare waiver, OHS cases are relatively expensive and the case-mix projections of the applicants show that a substantial portion are Medicare cases. If market demand and referral patterns suggest that new cases would be treated at existing providers, then the impact of the Medicare Waiver test will be lessened if the Medicare payments to the new provider are less than the Medicare payments to existing providers. If the new cases are treated out-of-state in the absence of a new provider, then none of the Medicare payments for those cases will be included in the waiver test. Therefore, the new program will have a negative impact on the Waiver test. Finally, if volume declines for existing providers as a result of a new program, then the existing providers’ rates will increase. The impact on the Medicare Waiver test under this scenario depends on the size of the incremental Medicare payments to existing providers relative to the incremental Medicare payments to the new provider. Previous analyses, however, have shown this impact to be very small. With respect to the cost-effectiveness standard, HSCRC indicated that this standard currently encourages hospitals interested in establishing new cardiac surgery programs to make competitive rate offers. HSCRC believes that this continued competitiveness encourages hospitals to keep overall costs lower for consumers, and would encourage MHCC to retain this standard.

•**Holy Cross Hospital** recommendation: Option 1, slightly modified. Holy Cross Hospital’s framework of balancing the advantages of size and the advantages of choice places significant weight to the cost saving aspects of additional choice. As such, Holy Cross Hospital supports giving preference to those applicants which offer the most cost effective program in any CON proceeding where the demand/capacity analysis does not support all of the applicants. This represents a balance of quality and savings to the public. If expected quality is the same, then the preference would go to the applicant(s) which the Commission, upon the advice of the HSCRC, believes would produce the greatest savings to the community.... Holy Cross Hospital believes that the Commission and HSCRC should review all the sources of savings in determining preferences, not only those savings embodied in a formal “offer”.

•**Johns Hopkins Medicine** believes the cost effectiveness should be considered, but quality measures and need are more important. Use cost along with other criteria, not as a deciding factor.

•**LifeBridge Health, Inc.** believes that the cost-effectiveness preference standard should be eliminated. It is important to keep in mind that creating new capacity will add real costs to the system.... The costs of expanding open heart surgical capacity will necessarily involve rate increases in other hospital services. While the overall State system may be maintained at a neutral reimbursement level, each individual hospital will have to find a number of ways to absorb the increased costs, including but not limited to higher charges to patients for other services, i.e., cost shifting. Either way patients pay for the increase in costs. Alternatively, a hospital facing such new costs could elect to abandon some element of its core community service mission by eliminating programs which appear to be relatively low-tech but in fact are relatively costly to provide.... Practically speaking, real competition already exists to foster price sensitivity.... Clearly managed care forces are actively operating to foster price competition and assure Maryland consumers reasonable rates. Even if this were not the case, HSCRC has the regulatory authority to address cost issues.

•In lieu of licensure based on quality of care standards, **St. Agnes HealthCare** is opposed to any cost effectiveness preference. The current standard which provides a preference in a comparative review for the most advantageous rate offer is nothing more than a component of a batched review process. Financial feasibility is already part of the review criteria, and the insurers have proven that they can favorably reduce the cost of care in these services through their contracting strategies. Further, recent conversion by the HSCRC to a case-rate reimbursement methodology for Maryland's hospitals negates the need for this preference standard.

•**Southern Maryland Hospital Center** believes that the existing policy of preference for hospitals with the most advantageous rate offer has undeniably resulted in substantial savings for the citizens of Maryland. It is, therefore, in the best interest of the health care system to continue with such a policy.

•**Suburban Hospital** recommends that a cost-effectiveness standard be maintained. However, the language in the 1997 OHS Section is confusing and should be revised to reflect changes in the rate regulatory system. Moreover, any revised standard should avoid a bidding-type process where applicants in a comparative review try to "go last" so that they can undercut others. Among other things, a revised policy should permit an applicant to meet rate offers made by others proposing new cardiac surgery service programs. This approach was followed in the most recent Central Maryland OHS Review.

•**The University of Maryland Medical Center** gives preference to Option 2 in the White Paper, eliminating the cost effectiveness standard. The pressures of managed care and the HSCRC's charge per case reimbursement methodology combined with competitive market forces are sufficient incentives to maintain low prices. Promoting a standard focused on unit rates of a particular service will not account for the impact on other charges that hospitals may re-allocate within the HSCRC's rate-setting methodology.

D. Access to Care Policies

1. Travel Time Standard

- ◆ **Option 1: Cardiac Surgery Services Should be Located Within 2 Hours, One Way Driving Time for 90 Percent of the Maryland Population**
- ◆ **Option 2: Cardiac Surgery Services Should be Located Within 90 Minutes, One Way Driving Time for 90 Percent of the Maryland Population**

• **Anne Arundel Medical Center** believes that the travel time standard ignores the reality of heart disease—the very real race against time faced by heart attack victims who go to community hospitals for help and care, and the critical importance of minimizing time between the advent of an incident and initiation of appropriate responses such as angioplasty, which may need OHS as a safety net back up. It is true that many heart attack patients can be safely treated by the infusion of medication, without the need for primary angioplasty, even though they may later need either PTCA or OHS. It is also not relevant. The issue is who should make the initial decision of which therapy is better suited to save the patient who comes to AAMC’s emergency room (by ambulance or car) in the midst of an MI? The highly trained team of physicians and health care professionals at the hospital, or the several hundred pieces of paper that comprise the new SHP chapter on OHS? OHS and angioplasty are not longer highly specialized services that must be rationed out without regard to the needs of any particular patient population in order to ensure that bad care is not being provided by under-trained, under-experienced OHS teams. That concept, like this standard, is a relic of the past.

• **Dimensions Healthcare System** believes that the travel time standard should remain at two hours as provided for in Option 1. The Baltimore-Washington region is already densely served by existing programs and travel time has never been identified as a special problem of access in this region. Similarly, there has been little problem with geographic access on the Eastern Shore. The establishment of a new program in Western Maryland will eliminate any significant geographic barrier to care in that region without loosening of this standard.

• **Frederick Memorial Hospital** questions the validity of current travel time standards with respect to PTCA. In light of the critical importance of minimizing time between a heart attack patient coming to the emergency room and receiving care, this standard may need to be limited to OHS alone.

• **Holy Cross Hospital** Recommendation: Either there should be no standard or the standard should be based on a realistic measure of emergency transportation time from the point of contact with the emergency system. There should be no driving time standards for elective, i.e., scheduled, OHS. People have shown, through their choices, that they will travel across country for elective OHS, much less drive for 2 hours. As a result, Holy Cross Hospital concludes that there should be no driving time standard as regards elective OHS. The current

standard could be replaced with a standard specific to emergency OHS. Holy Cross Hospital has no specific recommendation for a substitute standard at this time.

- Johns Hopkins Medicine** supports changing this standard to 90 minutes.

- In lieu of licensure based on quality of care standards, **St. Agnes HealthCare** is opposed to drive time as a measure of patient access to care and recommends the use of time to definitive treatment. This policy ignores the reality of heart disease. The various options presented fail to recognize the importance of response time between the advent of a cardiac event and initiation of definitive treatment versus the dysfunction of the existing patient transfer system. A more important access criterion than drive time, would be time to treatment. In Maryland, what is the actual time to definitive treatment for the majority of patients arriving at the emergency rooms of the community medical centers around the State? As noted earlier, the most recent clinical studies are finding improved patient morbidity and mortality when definitive treatment (angioplasty) is initiated within 90 minutes of arrival at the emergency room. This standard is well below the 2-hour drive time, and most likely not achievable in Maryland under existing CON laws.

- Southern Maryland Hospital Center** believes an appropriate travel standard for elective cardiac surgery could be either 2 hours or 90 minutes. However, the White Paper does not discuss the critical travel time/access issue: the need for prompt intervention in the form of angioplasty for patients suffering from acute myocardial infarction. If the Commission were to establish a travel time standard for angioplasty, it would surely be much less than 90 minutes--probably no more than 30 minutes. And, so long as the prevailing standard of practice (and/or the co-location policy in the SHP) requires cardiac surgery backup for angioplasty, the travel time standard for cardiac surgery effectively establishes the travel time standard for angioplasty. For this reason, we believe that the travel time standard for cardiac surgery services should be no more than 30 minutes.

- The **University of Maryland Medical Center** supports Option 1, a two-hour one-way driving time for 90 percent of the Maryland population. The Medical Center has not experienced any barriers to quality of care utilizing the current standards.

E. Other Policies

1. Eligibility to Meet Identified New Need

- ◆ **Option 1: Limit Eligibility to Meet Identified New Need for Cardiac Surgery Services to Hospitals Without Existing Programs**
- ◆ **Option 2: Expand Eligibility to Meet Identified New Need for Cardiac Surgery Services to All Hospitals**

•The current plan limits applicants to those that do not have an OHS program. The White Paper contains an option for existing programs to compete to meet an identified need. **Adventist HealthCare, Inc.** supports that option.

•**Anne Arundel Medical Center** believes that any OHS capacity at an existing provider over the SHP minimum quality of care volume should be disregarded, the regional “need” methodology should be eliminated, and the sole focus of any CON review should be on the individual hospital’s ability to provide quality cardiac care to its own historical patient base. Any hospital that can provide the service at the necessary volumes at reasonable cost should be permitted to serve their patients. Neither option is necessary.

•**Greater Baltimore Medical Center** believes that any OHS capacity at an existing provider over the SHP minimum quality of care volumes should be disregarded, the regional “need” methodology should be eliminated, and the sole focus of any CON review should be on the individual hospital’s ability to provide quality cardiac care to its own historical patient base. Any hospital that can provide the service at the necessary volumes should be permitted to serve their patients. Neither option is necessary.

•**HSCRC** agrees with the second option and would argue that, if hospitals with existing programs were able to compete to serve future need, competition may be increased and capacity and equipment expenditures associated with cardiac surgery decreased.

•**Holy Cross Hospital** recommendation: Option 1. The balance between size and choice requires that growth in a region create the opportunity for additional choice. Thus, only new applicants should be eligible for approval to meet new need. Existing providers can certainly tap into new demand if the public chooses them. But the public will never get the chance to not choose them unless Option 1 is selected. Further, while all “have nots” would be eligible, it would make sense to give preference to applicants that offer a greater increase in “choice”. That might include hospitals that are independent of the region’s existing providers, and, possibly, hospitals that will bring new OHS surgical groups into the region.

•**Johns Hopkins Medicine** believes existing and new programs should be eligible to meet new need.

•Under the **St. Agnes HealthCare** proposal, any OHS capacity over the threshold volumes adopted as part of the quality of care standards at an existing provider would be disregarded, the regional “need” methodology would be eliminated, and the sole focus would be on the individual hospital’s ability to provide quality of care to its own historical patient base in need for cardiac care.

•**Shore Health System** endorses Option 1. This standard will allow for increased access in open-heart surgery services.

•**Southern Maryland Hospital Center** believes that the CON system has always included the consideration of whether a projected need can be met more cost-effectively by a new provider or existing ones. In fact, it is included in the Commission’s CON review criteria: COMAR 10.24.01.08G(3)(c). Thus, there is no need for a new policy in this area.

•**Suburban Hospital** supports Option 1 which would limit eligibility to meet identified new need to hospitals without an existing program. Under Suburban’s methodology, for programs below the 40 percent cap, capacity is measured as highest volume achieved in the last three years. Hence, new cases would be reserved for existing providers if their more recent capacity was below the three-year high.

•The **University of Maryland Medical Center** believes that existing programs should, in fact, be given preference in all specialized services when considering how to meet new need. Current methodologies for use rate projections have (in some cases) dramatically overstated actual utilization. To then presume that new need identified by these projections can only be met by a new provider would seem to suggest that this new providers would have set up a program not to accommodate new need (since it didn’t materialize), but to pull existing volumes away from established programs. When new need is identified, current policies do not marry it with available capacity and thereby attempt to minimize the risk associated with overly optimistic projection methodologies.... Policies should consider new need and existing capacity in the same context.

2. Hospital Size

- ◆ **Option 1: Require Applicants for New Cardiac Surgery Programs to Have an Average Daily Census of at Least 100**
- ◆ **Option 2: Require Applicants for New Cardiac Surgery Programs to Have an Average Daily Census of at Least 200**
- ◆ **Option 3: Eliminate the Hospital Size Approval Policy**

• **Adventist HealthCare, Inc.** supports the elimination of the current Plan standard requiring that a hospital must have an average daily census of at least 100 patients over the past two years, and an 8-bed fully-staffed ICU. This standard may be waived by the Commission. Adventist HealthCare has reviewed no documentation which suggests that the size of the hospital, its census, or the size of its ICU has any bearing on the quality or performance of OHS programs. The capabilities of a particular hospital to meet the needs of OHS patients is secondary to the determination that a new OHS program is needed.

• **Anne Arundel Medical Center** believes that hospital size is important as a surrogate for other factors, including the sophistication of the medical staff and the adequacy of financial and operational resources. Small hospitals are far less likely to possess the physician, staff, and financial resources needed for a successful OHS program. However, ADC is a particularly crude measure of hospital size. It tends to penalize hospitals with a short length of stay or a large obstetrical program, and benefit hospitals with excessive ALOS. Almost everything else in the health care system is working to reduce ALOS, and it would be perverse to encourage higher ALOS as a measure of OHS worthiness. AAMC believes it would be more appropriate to measure a combination of factors, not just ADC. The number of admissions, emergency department volumes, size of the medical staff, or number of forced referrals for OHS or angioplasty could be considered. There is no reason advanced at all for adopting an ADC of 200, and little reason to support Option 1's de minimus requirements. AAMC suggests that admissions and emergency department volumes would serve as a better measure, and suggests a minimum of 16,000 admissions (including births) and 40,000 emergency room visits annually. These numbers would include most (though not all) of the State's existing "haves", and remain high enough to ensure the availability of adequate resources.

• **Carroll County General Hospital** supports Option 3. The number of beds is irrelevant if the quality outcomes are met.

• **Greater Baltimore Medical Center** believes that hospital size is important as a surrogate for other factors, including the sophistication of its medical staff and the adequacy of financial resources. Small hospitals are far less likely to possess the financial, staff and physician resources needed for a successful OHS program. However, ADC is a particularly crude measure of hospital size. It tends to penalize hospitals with a short length of stay, or a

large obstetrical program. We believe it would be more appropriate to measure a combination of factors, not just ADC. The number of admissions, emergency department volumes, size of the medical staff, or number of forced referrals for OHS or angioplasty could be considered. However, there is no reason advanced for adopting an ADC of 200, and there is little reason advanced to support Option 1. GBMC suggests that admissions and emergency department volumes would serve as a better measure, and suggests 16,000 admissions (including births) and 45,000 E. D. visits annually.

•**Holy Cross Hospital** recommendation: Option 2, modified. Since, up to a point, there is a clear advantage to successful and sizeable programs and the support infrastructure associated with a large institution, it makes sense to have a standard which limits applicants to those most likely to have a large, successful program. Screening out some applicants also makes the decision process more efficient.... Holy Cross Hospital would modify Option 2 to include as eligible an asset merged system that does not have OHS in the planning region and which has an ADC greater than or equal to 200 in the planning region. Three Maryland providers in the Washington Metropolitan area have an ADC in excess of 200 (WAH, PGGH, and Holy Cross).... If the Commission does not want to limit the number of eligible applicants to one, then it could adopt a threshold of 150 and give some preference to additional size above the threshold. (A threshold of 175 would qualify only two suburban Maryland hospitals, Holy Cross Hospital and Shady Grove Hospital). In addition to considering ADC, the Commission should consider the number of admission in MDC 5 and the number of ER visits for coronary related reasons. Holy Cross Hospital believes it may be reasonable to, at least, consider giving a preference to an applicant that is bigger in these two coronary related areas, as well as for overall inpatient size.

•**Johns Hopkins Medicine** believes that a minimum size of 100 ADC is acceptable.

•**Shore Health System** endorses Option 3 (or develop a policy that specifically addresses the intent). Hospital bed size does not in and of itself provide any specific relevant information ...for example, the latest trend in health care institution planning is often called “focused hospitals”. These institutions that specialize in cardiac care are called “Heart Hospitals” or “Institutes”. Though they are occasionally affiliated with large medical institutions, they are also “stand alone” institutions with as few as 60 beds.

•**Southern Maryland Hospital Center** would rank Option 3 as the best approach, Option 1 as the second best, and Option 2 as the least preferred approach. Assuming that the State Health Plan includes a minimum volume standard based on the number of cardiac surgery cases, a hospital size standard is unnecessary and redundant. A hospital which can generate and treat in an effective and efficient manner more than 200 cardiac surgery cases per year would have the capacity of operating a successful program, regardless of the overall number of patients in the hospital....If there is to be a hospital size standard, it should be based on the number of cardiac patients rather than the number of patients of all kind.

•**Suburban Hospital** believes that hospital size, whether measured by licensed beds, average daily census, or staffed ICU beds, is unrelated to a hospital’s ability to operate a successful cardiac surgery program.... As noted in Option 3, there are many other factors relevant to a hospital’s ability to implement a successful program and achieve the minimum and

threshold volumes. Indeed, the existence of the minimum and threshold volume requirements obviates the need for this standard. However, if the Commission decides to retain the hospital and ICU size standards, Suburban supports the 1999 TAC recommendation that the measures in the 1997 OHS Section (100 patient ADC and 8 bed fully staffed ICU) be maintained.

3. Number of New Programs Allowed

◆ **Option 1: Permit One New Cardiac Surgery Program at a Time in Each Regional Service Area**

◆ **Option 2: Eliminate the Limit on the Number of New Programs that Can Be Approved at One Time in Each Regional Service Area**

• **Adventist HealthCare, Inc.** supports the current Plan standard, which limits the number of new OHS programs that can be approved at one time in each of the four regional service areas.

• **Anne Arundel Medical Center** strongly opposes Option 1. The one program at a time, or controlled growth, approach has greatly contributed to the wastefulness of the CON program in the past. AAMC also notes that Option 1 has had a very low success rate. Despite the many thousands of dollars wasted on consultants and attorneys, the countless hours of time wasted in hearings, only four new programs have been granted a CON for OHS under the SHP.... The consolidation hearing process created by the combination of regional need and one program at a time has benefited consultants and attorneys at the expense of our patients. It must not be permitted to continue.

• If PCTA is approved without on-site cardiac surgery all hospitals should have the ability to offer this service. **Carroll County General Hospital** supports eliminating the limit on the number of new programs that can be approved at one time in each regional service area as provided under Option 2 of the White Paper.

• **Dimensions Healthcare System** believes that the existing policy in Option 1 of limiting new programs to one program at a time serves a valuable purpose in allowing the new program time to train staff, recruit its surgeon and establish its referral base without undue difficulties. Conversely, the existing programs would suffer much less disruption through loss of staff or volumes if only one new program at a time is established. Given the demonstrated association of volume and quality and the necessity of well-trained surgical teams to the provision of high-quality services, unnecessary disruption should be avoided.

• **Greater Baltimore Medical Center** strongly opposes Option 1 -- the one program at a time approach has greatly contributed to the wastefulness of the CON program. We also note that it has a very low success rate -- only three new programs have been granted CON under the

SHP, and one of them (Prince George's) has never met the minimum standard. The consolidated hearing process created by the combination of regional need and one program at a time has benefited consultants and attorneys at the expense of our patients. It must not be permitted to continue.

•**Holy Cross Hospital** recommendation: Option 2. In accord with our planning framework, Holy Cross Hospital believes that if need were sufficient to support more than one additional program, then it would be inappropriate to approve fewer additional choices and to artificially limit additional access. The primary competition new providers face is from existing providers, not from other new providers. Most new providers succeed by retaining cases they are currently referring away, not, primarily, by attracting cases from their major competitors.

•**Johns Hopkins Medicine** believes one new program should be permitted at a time to evaluate market impact.

•**St. Agnes HealthCare** strongly opposes the one program at a time approach that has so contributed to the wastefulness of the CON program. We also note that it has a very low success rate—only three new programs have been approved and opened under the various iterations of the SHP on open heart services, and one of them (Prince George's) have never met the minimum standard. A 33 percent failure rate should be evidence enough that this system has failed.

•**Southern Maryland Hospital Center** believes that the existing standard is generally appropriate, for the reasons stated in the White Paper. On the other hand, if the Commission were to make a policy decision to encourage local access to cardiac care by reallocating need from District of Columbia hospitals to Maryland hospitals, it might be appropriate to allow the approval of more than one program at a time.

•**Suburban Hospital** supports the current “one at a time” approach.

•**The University of Maryland Medical Center** believes that the number of new programs should be limited to one at a time in each regional service area.

•**Washington County Health System, Inc.** believes that there should not be a limitation on the number of new programs allowed in a specific region by the Commission. If in fact the volume and need is demonstrated within a particular region to support two programs above minimal capacity standards that are established by the Commission, then such programs should be allowed to be developed.

4. Preference Standards in Comparative Reviews

- ◆ **Option 1: Give Preference to Applicants Demonstrating Service to Minority and Indigent Populations and Having an Established Cardiovascular Disease Prevention Program**
- ◆ **Option 2: Eliminate Preference Standards**

•The current Plan standard is an effective incentive for potential future OHS hospitals and their medical staffs to improve service to minorities and indigents and to implement a cardiovascular disease prevention program. **Adventist HealthCare, Inc.** does not believe there is a reason to change this standard.

•**Anne Arundel Medical Center** believes that preferences must be eliminated along with the comparative reviews that created the need for them. However, some of the concepts set forth in the preference standards are valuable, and could be made mandatory. OHS does not exist in a vacuum, and hospitals that offer a full cardiac care program should offer prevention and education programs, outreach programs, and service to disadvantaged populations—including women. These are essential features of an effective continuum of cardiac care.

•**Dimensions Healthcare System** believes that strong preference should be given to institutions with special missions, including care for the indigent. Option 1 should not only be retained, but should be broadened to include other factors, i.e., medical education, designated trauma centers (particularly in counties where there is only one), service to minorities, the indigent and the underserved, and integrated systems seeking to establish a continuum of care. This policy should also serve as a criterion with respect to the protection of existing programs. In a comparative review in which one applicant could harm an existing program meeting one or more of these criteria and one applicant would not have such an effect, the latter program should be awarded the CON.

•**Greater Baltimore Medical Center** believes that preferences should be eliminated as vestiges of the comparative review we oppose. However, some of the concepts set forth in the preference standards are valuable, and should be mandatory – i.e., prevention and education programs, outreach programs and service to disadvantaged population. These are essential features of an effective continuum of cardiac care that the Plan should promote rather than hinder.

•**Holy Cross Hospital** recommendation: Option 1. For the reasons stated in the White Paper, as well as continued unexplained evidence of lower use rates for minority and indigent populations, Holy Cross Hospital supports Option 1.

•**Johns Hopkins Medicine** believes that preference should be given to programs serving minority and indigent populations. In both metropolitan Baltimore and metropolitan Washington,

we should all be concerned about the differences in the patterns of care provided to minority populations and women as compared to Caucasian men. Any methodologies to measure the trends in cases should take into account need for services versus demand for services. We need to better utilize our resources in identifying and caring for patients in need for services who are not receiving them. This problem transcends socioeconomic boundaries.

•**LifeBridge Health, Inc.** believes that the standard giving preference to applicants demonstrating service to minority and indigent populations and having an established cardiovascular disease prevention program should be retained as stated in Option 1. Current programs have the capacity necessary to address any increase in need that may be identified by increasing access for currently underserved populations. Therefore, the burden on new applicants to show that they are able to serve these populations should be very high.

•**St. Agnes HealthCare** believes the preferences should be eliminated as vestiges of the comparative review we oppose. Instead, St. Agnes supports the use of performance standards as critical and mandatory—i.e., chest pain centers, prevention and education programs, outreach programs and service to disadvantaged populations should be and are part of the approach to cardiac care.

•**Southern Maryland Hospital Center** believes that while the preference standards in the current plan represent laudable goals, we believe that it is unnecessary and potentially counter-productive to define preference standards so precisely. The Commission always has the responsibility of weighing the various merits of competing applicants in a comparative review, and it is often impossible to predict in advance exactly what the merits of the various programs may be. For this reason, we recommend Option 2.

•**Suburban Hospital** supports the existing preferences involving service to minorities and the indigent population and focusing on existing cardiovascular disease prevention programs. Suburban proposed that an additional preference be added in connection with applicants whose proposals involve a research project of national significance. The “national importance” criteria, as used under the existing CON exemption, should be the qualifier for this preference.

•**The University of Maryland Medical Center** believes that preference should not only be given to existing providers, but also to those institutions with demonstrated track records in providing care for underserved populations. As one of the state’s academic medical centers, it is part of our mission to provide care to underserved populations. This mission is not necessarily shared by other hospitals. As one of the State’s leading providers to minority and underserved populations, UMMC is working to ensure that all Marylanders have equal access to such specialized services as open heart surgery.

5. Exemptions from State Health Plan Policies

- ◆ **Option 1: Provide that the Full Commission May Waive Policies in the State Health Plan for Research Projects for a Limited Time with Conditions**
- ◆ **Option 2: Eliminate the Provisions Governing Exemptions from State Health Plan Policies**

• **Adventist HealthCare, Inc.** believes that current State plan standards are a reasonable mechanism for the Commission to encourage research projects on health service innovations, such as C-PORT and its successor. Adventist does not see a reason for a change.

• **Anne Arundel Medical Center** supports Option 1, but recognize the problems inherent in any such programs. A research project can end for many reasons, including loss of funding.

• **Carroll County General Hospital** supports Option 1. Keeping this policy will allow for exceptions, such as C-PORT, to meet the special needs and circumstances of research projects that will meet a national need and for which local conditions offer special advantage.

• **Greater Baltimore Medical Center** is a teaching hospital that supports Option 1.

• **Holy Cross Hospital** recommendation: No preference. Holy Cross Hospital has no strong preference here. C-PORT study is no longer research and primary angioplasty should be decoupled from OHS. While Holy Cross Hospital can not think of any likely use of this discretionary power by the Commission, some future research protocol might justify an exemption.

• **Johns Hopkins Medicine** strongly advocates provisions allowing the full Commission to grant exceptions for research for a limited time.

• **St. Agnes HealthCare** supports Option 1, but recognizes the problems inherent in any such programs. Hospitals may be reluctant to participate in research projects that cost a great deal of money and can be shut down for reasons outside of their control, including lack of funding.

• **Southern Maryland Hospital Center** recommends Option 1 for the reasons stated in the White Paper.

• **Suburban Hospital** supports the continuation of the existing exemption for research projects of limited duration.

•The **University of Maryland Medical Center** endorses Option 1. The Maryland Health Care Commission should have the authority to waive policies in the State Health Plan for a limited time with specific conditions related to research projects.

6. Relocation of Existing Cardiac Surgery Capacity within Merged Asset Hospital Systems

♦ **Option 1: Merged Hospital Systems May Not Relocate Any Part of an Existing Cardiac Surgery Program to Another Hospital Within its System without Obtaining an CON**

♦ **Option 2: Merged Hospital Systems May Reconfigure an Existing Cardiac Surgery Program to Another Hospital Within its System Under the Exemption Process**

•Current State Plan standard does not permit the relocation of any part of an existing OHS program to relocate to another Hospital without obtaining a CON. **Adventist HealthCare, Inc.** believes that this prohibition may be too broad. There are circumstances under which merged asset systems may appropriately relocate OHS capacity to improve geographic access or for other benefit.

•**Anne Arundel Medical Center** believes that either proposal absolutely ignores all of the reasons presented for having a State Health Plan for OHS in the first place. We support governing OHS programs through quality of care standards, including but not limited to volume standards, which focus on the particular needs of the single hospital (and its patients) under review. These options totally ignore quality of care and the correlation between volume and outcomes that were the initial impetus for regulation. There is no reason for either option other than to further benefit the “haves” at the expense of the citizens of the state. Hospitals in a merged system should have the same ability to offer OHS that we are urging for every hospital—no more and no less.

•**Carroll County General Hospital** supports Option 1. Each hospital should have to stand on its individual merit and not be able to transfer services from one to the other.

•**Greater Baltimore Medical Center** believes that either proposal absolutely ignores all of the reasons for having a State Health Plan for OHS in the first place. We support governing OHS programs through quality of care standards, including but not limited to volume standards. These options ignore quality of care and the correlation between volume and outcomes that were the initial impetus for regulation. There is no reason for either option other than to further benefit the “haves” at the expense of the citizens of the state.

•The **HSCRC** would not be supportive of the sharing of a CON between hospitals within a merged asset organization. HSCRC believes that transferring a portion of an existing cardiac surgery program to another hospital of a merged asset system would permit the proliferation of cardiac surgery services (and the capital and equipment expenses associated with the service) without the current regulatory review process that is necessary to ensure quality patient care and cost control mechanisms.

•**Holy Cross Hospital** recommendation: Option 1. First, the promotion of choice should favor real choices, not division of what is essentially the same choice. If size and choice matters, then splitting a single provider is not the best way to have the marketplace unfold.... In addition, the legislative intent is to encourage merger and consolidation, not just merger. Consolidation is discouraged by allowing duplication of programs within an asset merged system. Holy Cross Hospital would support a policy that allowed the relocation of an entire OHS service within a merged asset system in the case of a hospital closure.

•**Johns Hopkins Medicine** believes that the Commission should restrict relocation of any part of an existing program—this constitutes a new program and should require a CON.

•**LifeBridge Health, Inc.** believes that merged asset hospital programs should be allowed to relocate an existing cardiac surgery program to another hospital within its system under the exemption process, as set out in Option 2. This option could potentially help the system be more responsive to changes in demographics and ensure access to the greatest numbers of patients.... We stress, however, that the relocation exemption applies only if the entire program is relocated. To move certain parts of the program would undermine all of the cost and quality goals discussed at greater lengths throughout this paper by sacrificing the cost efficiency and quality that came with higher volumes.

•**St. Agnes HealthCare** strongly supports Option 1 in the absence of a licensure based regulatory approach. The implementation of Option 2 would only increase the competitive and economic advantage of the exiting OHS providers. As we have discussed, the combined effect of the existing regulatory process and insurance strategies is causing significant harm to community medical centers without this capability. Option 2 would allow a haphazard proliferation on additional OHS based solely on the premise of belonging to a merged system without balancing organization ability or patient need. This process would render facilities like St. Agnes, powerless to protect our already threatened clinical service. Option 2 absolutely ignores all of the reasons for having a SHP for OHS in the first instance. This option would be tantamount to total deregulation, but only for a select few. While we also challenge the effectiveness of and need for a CON for OHS, we would replace it with a quality of care oriented approach such as licensure. This proposal does neither, and is a recipe for disaster that will only serve to further entrench the “haves” current view as the CON as a franchise—something to be milked for its economic value.

•**Southern Maryland Hospital Center** recommends Option 1. However, the policy could be liberalized at least to the extent of permitting relocations of a program within the same planning region. This could provide some flexibility without violating the principles of regional planning.

•**Suburban Hospital** supports the existing State Health Plan requirement that a CON be obtained if a merged asset system proposes to relocate an existing open-heart surgery program from one hospital to another.

•**The University of Maryland Medical Center** believes that relocating existing programs from one hospital to another--even if they are in the same system--constitutes a new program and therefore should require a CON.

7. Other Issues

•**Adventist HealthCare, Inc.** believes that “waiting times” would be an appropriate standard to include from the past SHP standards to gauge the need for additional OHS capacity.... There is no current standard that allows the consideration of geographic location in selecting among competing applicants to meet an identified need in a planning region. Adventist HealthCare recommends that a new standard be adopted that allows such consideration...The State Health Plan should support a study of whether use of OHS services by women and minorities reflects a lack of access. Numerous studies in the medical literature have sought to address the reasons for the reported differences in use rates of specialized cardiac care services between women and men and between blacks and whites....There have been suggestions made that the apparent “underuse” of specialized cardiac services, such as PTCA and OHS, among blacks and women may indicate that the total needs of Maryland residents are not being considered in the Commission’s historical use-rate methodology. None of the studies we have reviewed makes this link between differences in use rates and unmet need. Furthermore, given the evidence that patient access to coronary angiography, a service that is widely available in Maryland hospitals, is a crucial determinant in the referral to revascularization, simply increasing the supply of hospitals that can perform OHS and elective PTCA may have no impact on “underuse” of these procedures by women and blacks. Adventist HealthCare believes that specific studies are necessary to determine if the differences in the rates of revascularization procedures in the Maryland population indicates a need for additional services such as primary care or prevention or a lack of availability of hospital-based services to minorities and women....The State Health Plan should include policies concerning the inter-hospital transport of cardiac patients as suggested by the TAC. The development of policies which address the inter-hospital transport of cardiac patients may provide a significant opportunity for Maryland hospitals to facilitate patient care access and increase the utilization of existing services.... There is a model for addressing the needs of cardiac patients for inter-hospital transportation. That model is the current system of inter-hospital transport in Maryland for selected specialty services. For example, in the case of low birth weight and premature infants who are born in hospitals which do not provide specialized neonatal services, transport to other hospitals with these capabilities is a routine matter across the state and within metropolitan regions.... Under the current system, the inter-hospital transport of cardiac patients is left largely uncoordinated and is carried out by primary ambulance companies. The group with the greatest responsibility

to reform the system are the providers of specialty cardiac services. This is the group to whom the State should look for the development of a system of inter-hospital transportation.

- **H. Carl Garthe** requested that the Commission take into consideration the preferences of patients and the community in terms of access during its deliberations related to planning and regulating open-heart surgery services in Maryland. GBMC enjoys a reputation for good quality medical care and has an outstanding facility, which is conveniently located in Baltimore County. A major hospital such as GBMC should have the ability to provide its patients the full continuum of care such as angioplasty and open-heart surgery.

- **MedStar Health** noted that in testimony before the Commission, the Washington Metropolitan Area cardiac service market was characterized as being dysfunctional because market share is primarily concentrated in two high volume programs with several low volume programs in the District of Columbia and a low volume program in Prince George's County. By contrast, the Baltimore regional market was characterized as more efficient or functional because market share is more evenly distributed among programs. The conclusion of this analysis was that adding more programs in the suburban Washington, D.C. market would make it more functional by providing greater choice for patients within Maryland. An alternative and more realistic explanation for the distribution of volume among programs in the D.C. is that it is the result of free market competition, where the two market leaders, because of their high volume, quality and efficiency are preferred choices of physicians, patients and payers.... Low volume programs is a reflection of programs that are not responsive to the market; not a reflection of the lack of programs.... The assumption of economic advantages to locating more programs in Maryland assumes patients and physicians will select low volume programs over established nationally recognized programs currently accessible to their communities there they live and work.

- The **Montgomery County Commission on Health** supports the recommendations of the Technical Advisory Committee to establish a statewide standard data set on patients with myocardial infarction, including the volume and characteristics of inter-hospital transfers. The Commission also believes that established cardiovascular disease prevention, early diagnosis, and patient education programs must be a part of every hospital's cardiac program. There must be documented evidence that the hospital has, or is committed to programs targeted to vulnerable groups, with an emphasis on minority populations. Mortality and morbidity rates should be reviewed to identify where racial and ethnic disparities exist for health outcomes. Special programs should be designed, in conjunction with local public health, to address these disparities.... Funding for prevention activities should be included in the hospitals' rates.

- **Suburban Hospital** believes that unlike Baltimore with its five, "right-sized" competitive programs, the D.C. market is dominated by a single large provider, the Washington Hospital Center. In 1999, the Hospital Center performed nearly three out of every four cardiac surgeries in the Washington region. Although nominally, there are six OHS programs in the Washington region, in fact, there are just two....The dysfunctional nature of the D.C. market is further demonstrated by the Hospital Center's increasing dominance. In 1994, the Hospital Center performed roughly 50 percent of all cardiac surgery in this area. The Hospital Center's already large market share, however, has increased dramatically over the last five years, i.e.,

from 50 to 75 percent....Hal Cohen, Ph.D. and Graham Atkinson, D.Phil. analyzed savings to payors generated by development of a new OHS program in the D.C. region. Unfortunately, their paper is limited to an assessment of savings to the Medicare program because the Hospital Center is located in Washington, D.C. and does not provide information to the HSCRC. Of course, necessary data would be available if this program was located in Maryland. In any event, the Cohen/Atkinson paper, demonstrates that if just 200 cardiac surgeries and 200 angioplasties were performed at either Suburban or Holy Cross instead of at the Hospital Center, savings to the Medicare program (and American people) would be \$4 million each year. These savings result from the rate offers that an existing Maryland-based program must make in connection with the CON approval process. This phenomenon, and price reductions in response to the new, lower-priced competition, both generate savings to payors. This is precisely what occurred in the Baltimore market as a result of development of the two new, competitive programs at Sinai and Union Memorial during the last several years. Given this experience and the current situation in the D.C. area, it is difficult to understand why the Commission should continue a policy that: (1) protects a non-Maryland hospitals from effective price competition; (2) denies Maryland consumers meaningful choice; and (3) causes the Medicare program to pay millions of additional dollars to a non-Maryland hospital for cardiac surgery provided to Maryland residents.